TITLE: A pragmatic adaptive trial of hope-focused mentoring to improve mental health and social outcomes for young women who are not in education, employment or training in deprived coastal areas

SHORT TITLE: The Looking Forward Project

Funder	**NIHR158476**
Research Ethics Committee	**IRAS 327723**
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Trial Registration	ISRCTN52288029

Protocol Version

Number	Date	Details
V1.0	26th March 2024	Original
V1.1	3rd May 2024	Minor clarifications added following University of Sussex Pre-Sponsorship Review Panel. Addition of midpoint contact for young women participants.
V1.2	28th May 2024	Sponsor reference number and details added following review by the University of Sussex Sponsorship Sub-Committee.
V1.3	11th July 2024	Changes made following REC panel review. Correction to title. Addition of one assessor-rated measure pertaining to young women participants. Clarification of secondary analyses pertaining to mental health problem prevention-related outcomes. Clarification of definition for end of study. Removal of HRA logo.
V1.4	18th Dec. 2024	Amendments made as set out in log below

Amendment Log

Number	Date	Details
AM01	18.12.24	Signature Page (p. 4): Dr Daniel Michelson's signature added.
AM02	18.12.24	Key Trial Contacts (p. 4-5): Dr Daniel Michelson added as Chief Investigator with Dr Clio Berry moving to Co-Chief Investigator; this temporary change is due to Dr Berry's maternity leave. Dr Saskia Berry added as Trial Statistician.
AM03	18.12.24	Public Summary (p. 10), Scientific Summary (p. 11) and Trial Setting (p. 21-22): Clarified that the research is taking place in coastal and proximal local authorities across Sussex, Kent and Norfolk without naming specific local authorities. This is a more accurate reflection of the geographic sampling frame (based on residence of participants) rather than implying direct involvement of local council services in trial delivery.
AM04	18.12.24	Oversight Groups (p. 12-14): In line with latest NIHR guidance, clarified that 75% independence criterion applies to committee membership overall rather than attendees at individual oversight meetings. Updated header row in table updated to repeat across pages. Updated TSC/DMEC membership to reflect arrangements at date of revised protocol. Updated Trial Management Group membership to include senior research staff. "Trial Working Group" renamed as "Trial Operational Group."
AM05	18.12.24	3.3 Secondary Outcomes (p. 20): Added Adverse Events Checklist and corrected EDAPTS among secondary outcomes. See corresponding details in AM12 below.
AM06	18.12.24	6.1 Eligibility Criteria for Young Women (p.22) & 7.4 Eligibility Assessment (p. 26): Added source reference for suicide screening tool. Clarified that eligibility also requires residence (based on postcode) corresponding to a local authority within Sussex, Kent or

		Norfolk; this geographic criterion was inadvertently left out from previous protocol versions.
AM07	18.12.24	7.1 Recruitment (p. 24): Clarified that recruitment via primary care may involve remote methods implemented by primary care staff and NIHR Research Delivery Networks.
AM08	18.12.24	7.6 Randomisation Scheme and Its Implementation (p. 26): Clarified that randomisation will be stratified by "relevant local authority area" without presupposing which local authorities will ultimately contribute participants.
AM09	18.12.24	7.9 Intervention Adherence, 7.11 Mid-point Contact & 7.12 Adverse Events (p. 28): Added that "other unblinded research staff" will contribute to the specified research activities in conjunction with Trial Manager.
AM10	18.12.24	7.10 Follow-up assessments: Clarified that remote data collection via REDCAP survey will be the default mode of self-reported participant data collection at 16 weeks and 12 months, but with an allowance for researcher support (in person or via video call) if needed.
AM11	18.12.24	7.11 Schedule of Procedures (p. 29-31): Updated header row in table to repeat across pages. Underlined sub-headings for clarity. Corrected TUS schedule to include 16-week and 12-month assessments (cells had been left blank in error). Updated adverse event/effect assessments to reflect changes in AM12 below.
AM12	18.12.24	7.12 Adverse Events (p. 28): Added self-reported Adverse Events Checklist that will be completed by all participating young women at 16-week and 12-month assessments to ensure balanced reporting between trial arms. Corrected name of EDAPTS scale (which measures Adverse *Effects* rather than Adverse *Events* of psychological interventions*).* EDAPTS complements the Adverse Events Checklist by providing a more differentiated assessment of potential psychological harms in the intervention arm specifically. For the sake of completeness, we have clarified that adverse events may also be detected spontaneously via verbal report from young women participants or mentors outside of research assessments.
AM13	18.12.24	8.1 HOPEFUL Together (Intervention; p. 31): Updated training of mentors to include 1:1 video call with a clinically qualified senior researcher.
AM14	18.12.24	8.2 HOPEFUL Future (Comparator; p. 37): Updated content of written handout for control arm, including acknowledgment that participants may wish to connect with a putative mentor if they wish (i.e., not ruling out the possibility of informal mentoring independently of the HOPEFUL intervention). This potential scenario will be explored in our process evaluation.
AM15	18.12.24	11.2 Definition of Adverse Events (p. 40-41): Following advice from the trial DMEC, details have been updated in terms that are more appropriate for a psychological intervention trial as opposed to a CTIMP trial. Also clarified distinctions between AEs, SAEs, ARs, SARs & SUSARs.
AM16	18.12.24	11.3 Recording and Reporting of Adverse Events (p. 41): Following advice from the trial DMEC, further details have been added to clarify operational procedures and external reporting timelines.
AM17	18.12.24	18 Gantt (p. 55): Updated Gantt chart to reflect operational start of trial in August 2024.

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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:
..../...../.....

Name (please print):

.....

Position:
.....

Chief Investigator:

Signature: .... Date:
28/05/2024

..... 17/12/2024

Key Trial Contacts

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List of Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
NEET	Not in Education, Employment or Training
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIP	Public Involvement Panel
PIS	Participant Information Sheet
QA	Quality Assurance
RA	Research Assistant
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure

SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

Trial Summary

Trial Title	A pragmatic adaptive trial of hope-focused mentoring to prevent mental ill-health and improve social outcomes for young women who are not in education, employment or training in deprived coastal areas
Short Title	The Looking Forward Project

Trial Design	Adaptive assessor-blind pragmatic open controlled superiority randomised trial with 1:1 allocation to HOPEFUL with mentoring plus usual support (HOPEFUL TOGETHER) versus waitlist for HOPEFUL workbook plus usual support (HOPEFUL FUTURE). The programme consists of two stages, a feasibility trial, followed by a definitive trial. Unless otherwise indicated by pre-specified progression criteria, the feasibility trial will become an internal trial stage and the feasibility sample will be subsumed into the definitive trial sample.	
Trial Participants	16–25-year-old NEET young women	
Planned Sample Size	Stage 1 (Feasibility): 70 participants Stage 2 (RCT): 248 participants Note: Stage 1 will be adopted into Stage 2, i.e., it will become an internal feasibility trial with the n = 70 participant subsumed into the 248 definitive sample, unless otherwise indicated.	
Intervention Duration	Up to 16 weeks	
Follow up Duration	12 months	
Planned Trial Period	Up to 54 months (Stage 1 14 months, Stage 2 up to 40 months)	
Objectives	Outcomes	Outcome Measures
Objective 1: Test the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) to evaluate HOPEFUL Objective 2: Refine the RCT design Objective 3: Conduct a definitive RCT Objective 4: Understand the processes and circumstances underlying intervention effects	Primary	Trait Hope Scale
	Secondary	Short Warwick-Edinburgh Mental Wellbeing Scale Depressive symptoms (Patient Health Questionnaire; PHQ-9) Anxiety symptoms (Generalised Anxiety Disorder scale; GAD-7) Social anxiety (Social Interaction Anxiety Scale and Social Phobia Scale combined SIAS-6 and SPS-6) Meaning in Life Questionnaire (MLQ)
		Time Use Survey (TUS)
		General Help-Seeking Questionnaire (GHSQ)
		Client Service Receipt Inventory (CSRI)

	Proposed mechanisms	Working Alliance Inventory Short Revised (WAI-SR)
		Goal Based Outcome Tool (GBOT)
Key Words	youth; NEET; functioning; women; community; mental health	

Public Summary

About 14% of UK 16-25-year-olds are not in education, employment, or training (NEET). The number of NEET young women is significantly growing. NEET young women have more mental health and social problems. There is little evidence about how to prevent this, although our recent research suggests that increasing hope can help. Hope can be defined as a mindset that is focused on meaningful goals. NEET young women especially struggle with hope. New solutions are needed to translate evidence about hope into practical support that young women can access and want to use.

We worked with NEET young women, their families, and youth workers in coastal areas to create a structured talking and activity-based programme called HOPEFUL. The aim of HOPEFUL is to increase hope and help NEET young women to work towards their goals and spend time in meaningful activities that benefit their mental health. HOPEFUL has six sections. It can be completed flexibly within 16 weeks with the support of a youth-initiated mentor. This means that NEET young women choose someone whom they already know and trust (e.g., a relative or sports coach). Each mentor receives training, supervision, and a support manual for HOPEFUL.

Our project first aims to check that it is possible to involve NEET young women and mentors in a trial of HOPEFUL. If so, our second aim is to do a large trial to test if HOPEFUL works and offers value for money. We will do these trials in coastal and nearby areas in Sussex, Kent and Norfolk.

For the first aim, we will do a small trial with 70 NEET young women to check they want to take part and can identify a mentor. All 70 will keep receiving usual support they already get (e.g., from social or youth services). Half will also be selected by chance to receive HOPEFUL. Those not selected will be given a HOPEFUL workbook after the trial. We will ask the young women to fill out surveys about their mental health, wellbeing, and activity at the start of the trial and again after 16 weeks. We will ask mentors how they have used HOPEFUL with the young women. We will monitor how many young women and mentors agree to take part, stay involved in the trial, and go on to complete HOPEFUL. We will interview 10 NEET young women and 10 mentors and ask what they liked and disliked about the trial.

For the second aim, we will do a larger randomised controlled trial with 248 NEET young women, including those from the smaller trial. We will test how HOPEFUL compares to usual support at increasing hope, reducing depression, anxiety, loneliness, and improving wellbeing, life meaning, structured time use and help-seeking – all of which lower the risk of developing serious mental health problems. We will collect information using questionnaires at the start of the trial, after 16 weeks, and after 12 months. We will also collect questionnaires from mentors and young women about relationship with each other during their time using HOPEFUL. We will also interview about 16 women and 16 mentors to explore their positive and negative experiences of HOPEFUL. We will work out the cost of delivering HOPEFUL and whether it is likely to lead to changes in employment, education, and support service use. This will allow us to assess value for money.

After these trials, we will finalise HOPEFUL and make it freely available. We will share our results with the government and organisations working with NEET young women. The vision is that HOPEFUL can be used widely by community organisations to prevent mental ill-health and improve life chances for NEET young women.

Scientific Summary

BACKGROUND: Young women who are not in education, employment, or training (NEET) are growing significantly in number. They have poorer mental health and social outcomes relative to young women who work and/or study and compared to NEET young men. Gender disparities are compounded in deprived coastal areas, in which NEET young women especially lack self-agency and aspirations. Research by our group and others shows that greater hope reduces the risks of staying NEET and of having mental health problems. We have developed a hope-focused intervention (called HOPEFUL) for this group. HOPEFUL is a flexible modular programme, delivered over 4-12 weeks, for creating a hopeful mindset and learning skills in setting and pursuing personally meaningful goals. Support is provided by a youth-initiated mentor; someone that NEET young women select from their existing network.

AIMS AND OBJECTIVES: We aim to conduct an adaptive trial to generate evidence on the feasibility, effectiveness, and cost-effectiveness of the HOPEFUL intervention. Our specific objectives are to test the feasibility of conducting a randomised controlled trial (RCT) to evaluate HOPEFUL and refine its design (feasibility trial), and then complete a definitive RCT with economic and process evaluations (definitive trial).

RESEARCH QUESTIONS Our primary feasibility research question is, is it feasible to recruit and retain NEET young women and mentors in a trial of HOPEFUL plus mentoring and usual support vs. usual support and access to the HOPEFUL materials at end of the trial, conducted in coastal and proximal local authorities in Sussex, Kent and Norfolk, with recruitment focused on deprived neighbourhoods? Our primary definitive RCT research question is, does HOPEFUL improve hope (primary outcome) and secondary outcomes of mental health symptoms, wellbeing, life meaning, time use, loneliness, and help-seeking of NEET young women at the primary endpoint of 16 weeks and secondary endpoint of 12 months post-randomisation compared to usual support services? Secondary research questions pertain to: intervention cost-effectiveness; how NEET young women and mentors experience HOPEFUL and its safety and acceptability; and mechanisms of intervention effects and contextual moderators.

METHODS: NEET young women (aged 16-25 years) will be recruited from young people's services provided by local authorities and the charity/voluntary sector, including employability and sexual health services. An adaptive trial design will incorporate a feasibility trial (N=70) with progression to a definitive RCT (N=248), assuming warranted. The trial will use 1:1 randomisation, stratified by local authority area, and age (16-18 versus 19-25 years). Feasibility outcomes will be assessed post-intervention (16 weeks), with a further endpoint of 12 months in the definitive RCT. The feasibility stage participant data will be subsumed into the definitive RCT outcome analysis unless otherwise indicated by feasibility results The RCT includes an economic and a multi-method, multi-perspective process evaluation.

TIMELINES: Total duration: 54 months. Months 1-12: feasibility trial. Months 13-14: analysis against pre-specified progression criteria and protocol amendments. Months 15-54: definitive RCT.

ANTICIPATED IMPACTS AND DISSEMINATION: We will disseminate findings using tailored outputs for participants, the public, academics, health and social care practitioners and commissioners, and policy-makers. In the short term, evidence generated through this project will raise the UK profile of youth-initiated mentoring and support local implementation. In the longer term, we anticipate practice impacts through scaled-up access to HOPEFUL. The ultimate goal is to improve the health and social outcomes of NEET young women and strengthen their networks, with associated economic and societal gains.

Support Given

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
NIHR Public Health Research Programme	Funder
Clinical Research Networks Kent, Surrey and Sussex and East of England	Support from research delivery teams for recruitment as per the trial's NIHR portfolio eligibility
Brighton & Hove City Council	Provision of mentoring supervision
Medway Council	Provision of mentoring supervision
East Sussex County Council	Provision of mentoring supervision
Norfolk County Council	Provision of mentoring supervision
Kent County Council	Provision of mentoring supervision
Xtrax youth service, Hastings	Provision of mentoring supervision
The Education People, Kent	Provision of mentoring supervision

Role of the Trial Funder and Sponsor

The Funder (NIHR) will be informed as to the progress of the trial against the specifications detailed in the contract. Other than monitoring and reporting, the Funder will not have responsibility for study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The Sponsor (University of Sussex) is responsible for ensuring that arrangements are in place for the research team to access resources and support to deliver the research as proposed and agreements are in place which specify responsibilities for the management and monitoring of the research. Other than approving the trial for sponsorship, and monitoring, the Sponsor will not have involvement in the study design, data analysis and interpretation, manuscript writing, and dissemination of results. The Sponsors will be informed on trial progress and consulted regarding any proposed changes to protocol or any protocol deviations. The Sponsor has financial and contractual oversight.

Roles and Responsibilities of Oversight Groups

This section provides an overview of the oversight groups for this programme. Specific activities are referred to where relevant beyond. The governance of these committees is the responsibility of and resides with the funder. The funder receives nominations from the research team. The funder scrutinises these individuals to ensure appropriateness. Appropriateness includes consideration of the individual's competence for the invited role. The consideration of appropriateness further includes that the chair and 75% of the committee membership must be independent of the research team. The funder defines independence as:

- Not part of the same institution as any of the applicants or members of the project team.
- Not part of the same institution that is acting as a recruitment or investigative centre, including Patient Identification Centres (PIC), identifying, and referring patients to a recruitment or investigative centre.
- Not related to any of the applicants or project team members.
- No other perceived conflicts of interest.
- For the Chair only; not an applicant on a rival proposal.

The list of individuals given below must be treated as indicated and not confirmed. Moreover, changes to membership may be made throughout the trial programme and will be done with the approval of the funder where relevant (TSC and DMEC). Members of the research team and/or other individuals may, with approval of the chair, attend the meeting as Standing Observers. Planned standing observers are listed below.

The exception to the nomination and approval process described above is the Public Involvement Panel (PIP). The funder mandates the creation of this oversight group, reviews its role and the regulatory with which it meets, and receives copies of its minutes. The nature of this group is that it comprises individuals with nuanced lived experience. These individuals must be sensitively identified, approached, and invited to join the committee. Such processes must themselves be led by individuals with relevant lived experience and must be mindful of considerations relating to equality, diversity, inclusivity, and access. Thus, the governance of the PIP is led by the Public Involvement Lead, with support from the programme partner Sussex Partnership NHS Foundation Trust.

Committee	**Purpose and make up**	**Members**
Trial Steering Committee (TSC)	The TSC holds responsibility for governing the scientific integrity of the trial. The TSC must have a majority independent representation, including the Chair, meet regularly and send reports to the funder. The TSC will comprise practitioner and academic experts, and approximately two public (lay) members.	Kathryn Abel, Professor of Psychological Medicine and Reproductive Psychiatry, University of Manchester; Professor Steve Pilling, Professor of Clinical Psychology & Clinical Effectiveness, University College London; Dr Rachel Brown, Research Fellow, Cardiff University; Dr Thees Spreckelsen, Senior Lecturer, University of Glasgow; Dr Fiona Warren, Senior Lecturer in Medical Statistics, University of Exeter Medical School; Dr Rhys Bevan-Jones, Senior Clinical Research Fellow, Cardiff University; Prof. Sheena Asthana, Co-Director of the Centre for Coastal Communities, University of Plymouth; Prof. Rachael Hunter, Professor of Health Economics, UCL; Abi Thomson (public member – Queen Mary University of London); Carley Hayes (public member – The Education People). Non-independent members/standing observers will include the co-CIs and other members of the TMG
Data Monitoring and Ethics Committee (DMEC)	The DMEC holds responsibility for governing the safety and ethical conduct of the trial. This excludes review of adverse events and unintended consequences and oversight of the safe and ethical use of data. The DMEC must have a majority independent representation, including the Chair, meet regularly and send reports to the chair of the TSC and the funder.	Prof. Mick Cooper, Professor of Psychology, Roehampton University; Dr David Curran, Senior Lecturer, Queen's University Belfast; Miss Jessica Green, Senior Statistician, Liverpool Clinical Trials Centre, University of Liverpool; Ashley Jones, Head of Statistics, Liverpool Clinical Trials Centre, University of Liverpool.

Committee	Purpose and make up	Members
		Non-independent members/standing observers will include the trial statisticians, TM and co-PIs.
Public Involvement Panel (PIP)	The PIP holds responsibility for consultation from a perspective of lived experience expertise. The PIP will provide guidance on ensuring that the trial programme is conducted in a way that is sensitive to the lived experience of those participating. The PIP will review performance of planned public involvement activities.	Approximately eight young women in Sussex, Kent and Norfolk areas who have recent (within five years) experience of being NEET.
Trial Management Group (TMG)	The TMG will meet on a monthly basis to ensure the trial is running as planned.	Co-PIs, protocol contributors and senior research staff.
Trial Operational Group (TOG)	The TOG will meet on a weekly basis to support and monitor participant recruitment and retention. Regional leads will be invited as needed for problem-solving purposes. The TM will meet separately with peer researchers at more infrequent points in the trial in order to monitor qualitative interview recruitment and completion.	Co-PIs, TM, research staff, regional leads (CB, LF, JW) at invite.

1 BACKGROUND

We address the poor health and social exclusion of 16-25-year-old women who are Not in Education, Employment, or Training. NEET young women outnumber NEET young men and suffer worse long-term mental health and social outcomes[1–3]. Caring roles and family unemployment are more likely to result in young women being NEET than men, and NEET young women are more likely to be bullied and harassed when trying to re-enter work and education[1,4–7]. "Scarring" effects mean that time spent NEET predicts mental ill-health and unemployment decades later[8]. The multiple disadvantages for NEET young women are compounded in deprived areas[9], especially coastal regions, which have fewer jobs, poor schools and infrastructure, and lower aspirations than deprived inland regions[10]. Yet structural factors do not dictate life trajectories[11]. Varying outcomes of NEET subgroups are mediated by differences in self-beliefs and appraisals[7,12]. Specifically, increasing hope raises aspirations and improves social and mental health[13–16]. Yet hope is depleted for NEET young people, especially so for women[11,17]. New solutions are needed to reduce these health and social inequalities.

We reviewed the literature in July 2023 and found only 15 studies that disaggregated mental health and social outcomes by sex/gender for English NEETs; only one of which tested an intervention (computer coding). What research does exist shows that, relative to young female workers and students and compared to already-disadvantaged NEET young men, NEET young women have poorer mental and physical health[1,3], more chronic health conditions[1], greater suicidality and self-harm[18], isolation[4,19], and are more likely to stay NEET due to mental ill-health[20]. This knowledge gap sits within the context of un-ameliorated coastal inequalities[21] and an ongoing crisis of youth service provision, in which NEET young people are especially unlikely to get help[22].

The current protocol focuses on "hope" as a key interventional lens for NEET young women living in coastal deprivation. Hope is the belief one can reach their goals (self-agency) and identify how to do so (pathways)[23]. Increasing hope is an efficient way of improving how people perceive and engage with their environments[24], for it is psychologically precise and self-reinforcing, with broad impacts[13]. An intervention to enhance hope has further direct relevance to NEET young women for the following reasons. First, NEET young people have less hope than other groups on average[11] and this is especially true for NEET young women[17]. Second, hope promotes positive mental health and reduces ill-health, reducing depression[13], providing resilience against anxiety and stress[25], reducing the impacts of adversity[11,26], and protecting young people against suicidal ideation and behaviour[27]. Third, hope predicts positive youth academic and employment outcomes[13–15] better than IQ and ability[28]. Hope motivates young people to be cognitively, emotionally, and behaviourally engaged in secondary and higher education[29], encouraging them in turn to perform adaptive and success-oriented behaviours[29] that bring about positive academic outcomes. Fourth, hope increases help-seeking[13], including participation in informal and formal psychotherapeutic support for mental health problems and suicidal thoughts[30]. Finally, evidence shows that people with greater hope are less likely to become NEET, or to stay NEET over time[11].

Importantly, young women particularly lack hope relative to young men when they live in remote areas[31], like coastal communities. As highlighted in the Chief Medical Officer's 2021 annual report[21], health policy and research in England have been slow to address the health and social inequalities in coastal communities and surrounding areas. Some of the starkest deprivation occurs in English seaside towns, where resident young people face transient job opportunities, under-performing schools, and long-term decline in infrastructure; all of which drive low levels of aspiration[10]. These environmental risks are compounded by relatively scarce provision of youth services and specialist mental health support, in the context of wider service fragmentation. NEET young women's hope is further undermined by the interpersonal discontinuity in youth services[32], and their families and communities projecting hopelessness about their possible futures[11,32]. Thus, there is a clear mandate for enhancing the hope of NEET young women, especially when living in coastal deprivation. The need is specifically for an effective, low-cost, sustainable solution that offers interpersonal continuity, is sensitive to the specific needs and preferences of NEET young women, and that embeds hope in their surrounding networks.

Our 2022 systematic review showed that hope can be increased in brief interventions with vulnerable young people and that doing so creates mental health and social benefits[13]. These interventions can be delivered in a variety of settings, including within the community, and can be supported by non-specialists[13]. We additionally found that hope can be reliably measured to show such effects[13].

We used a 2022 Application Development Award (ADA[32]; NIHR135316) to develop the HOPEFUL intervention. To embed hope in the fabric of NEET young women's lives, in the context of projected pessimism in their networks and fragmented services with high staff turnover, we scoped the literature to identify an innovative "youth-initiated mentor" model[33,34] originating in Europe and the United States and not previously evaluated in the UK. This means NEET young women select someone they already know and trust to support them with HOPEFUL, e.g., a non-parental relative or sports coach. The mentor is trained in the principles and methods of the HOPEFUL intervention, which they implement flexibly in the context of their existing relationship with the young woman. Outside the UK in Europe and the USA where it originates, youth-initiated mentoring has been shown to improve mental health and social functioning for disadvantaged youth[33,34]. The model is highly relevant to England's under-resourced coastal areas, as it requires fewer resources than professional mentoring (or other professional-led interventions)[33,34], whilst building community capacity to support vulnerable young people in the longer-term.

2 RATIONALE

The current proposal will evaluate whether HOPEFUL works and offers value for money. This is important to public health for several reasons. The number of NEET young people is large (14% nationally) and is growing; significantly so for young women[2]. There is a pronounced lack of research on NEET young women. Limited data that are available show this group experiences the least positive beliefs about themselves and the future, the lowest aspirations, and the poorest health and social outcomes. Despite these inequities, Public Health England[35] and scientific reviews[36] show a dearth of evidence-based interventions for NEET young people and none for NEET young women specifically. A context-sensitive, scalable, and sustainable solution to reduce these health and social inequalities is needed. Local authorities, commissioners, and voluntary and charity services in our proposed research areas agree that HOPEFUL is relevant, novel, and fits with local priorities and future commissioning intent.

Our overarching aim is to evaluate the acceptability, effectiveness, and cost-effectiveness of HOPEFUL as a means to enhance the hope, mental health, and social outcomes of NEET young women in deprived coastal areas. To achieve this aim, we plan to conduct a randomised controlled trial (RCT) and must first ensure that this is feasible. In our ADA[32], we prototyped an intervention with the potential to be acceptable and feasible. Through a series of interactive co-design activities, NEET young women endorsed the acceptability and feasibility of the following intervention components: a modular structure, covering six domains in a specific sequence (see Section 8); a flexible menu of selectable activities per module, with specific examples for each; animated videos for psychoeducation; intervention materials offered on paper and digitally; a companion manual for mentors and their supervisors focusing on the intervention principles; being youth-centred; and an explicit focus on hope as a primary outcome. However, we did not evaluate its effects or user experience directly.

We have recruited NEET young people to observational research[22,37] and RCTs[38], at the rate of recruitment we propose here (10 per month). Practitioners in the ADA[32] expressed a desire to refer suitable individuals. However, there is uncertainty regarding the willingness of NEET young women and prospective mentors to participate in a trial of HOPEFUL plus usual support *versus* usual support alone. Therefore, we propose to first test whether a definitive RCT is feasible, particularly with respect to recruitment and retention of NEET young women and mentors, and data completeness. Pre-specified progression criteria are presented in 3.1. Our objectives and their aligning research questions are as follows.

Objective 1: Test the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) to evaluate HOPEFUL:

1.1. Is it feasible to recruit and retain, with complete data, NEET young women and mentors in a randomised controlled trial of HOPEFUL plus usual support *versus* usual support alone?
1.2. Can HOPEFUL be delivered as intended and do NEET young women and mentors form positive mentoring relationships?
1.3. How do NEET young women and mentors experience trial participation and HOPEFUL?

Objective 2: Refine the RCT design:

2.1 What is the estimated standard deviation of the Trait Hope Scale (primary outcome) in NEET young women?
2.2 What do NEET young women consider to be the minimum meaningful change in this measure of hope?
2.3 What changes, if any, are needed to increase acceptability and feasibility of the intervention and research protocols?

Objective 3: Conduct a definitive RCT:

3.1 Does HOPEFUL improve hope (primary outcome), mental health, wellbeing, life meaning, time use, loneliness, and help-seeking (secondary outcomes) of NEET young women relative to usual support services, at 16 weeks (primary endpoint) and 12 months post-randomisation?
3.2 Is HOPEFUL cost-effective in terms of costs and the primary outcome measure and wellbeing?
3.3 How do NEET young women and mentors experience HOPEFUL and its effects, safety, and acceptability?

Objective 4: Understand the processes and circumstances underlying intervention effects:

4.1 Do the mentoring relationship and goal attainment during HOPEFUL mediate change in hope, and does hope mediate change in secondary outcomes?
4.2 Under what circumstances and for whom is the intervention more likely to work (and to not work)?

Our evaluation approach draws on Medical Research Council (MRC) guidance for evaluating complex interventions[39,40], seeking to not only understand if the intervention works at the group level, but also how the intervention was implemented, what mechanisms explain the effects, and what contextual factors would likely affect implementation and outcomes if scaled-up. The interpretation of the RCT and process evaluation results will be informed in part by the theoretical foundations of the HOPEFUL intervention. First, following from Snyder's influential cognitive model[23], we conceptualise hope as a mindset comprising goal-directed, self-agentic thoughts and the ability to identify pathways towards personally meaningful goals[41]. Previous work with young people[13], including NEET young women in our previous ADA[32], confirms that this model aligns with their "lay" conceptualisations of hope. Second, we have situated HOPEFUL within the "wise" intervention approach[24]. Wise interventions are those which, unlike traditional social reforms that target either individual capacity or the environment, conceptualise the person and situation together; targeting specific psychological processes to improve health through augmenting person-environment interactions[24]. HOPEFUL does this in a psychologically precise[24] and efficient way by targeting hope, which is self-reinforcing[13] and has broad impacts. HOPEFUL additionally recognises that person-environment interactions occur in complex causal systems[24], for hope enables NEET young women to take advantage of socio-occupational and support opportunities around them where these exist. The proposed youth-initiated mentor further encourages recursive change[24], for it embeds the intervention directly into NEET young women's lives.

The practical application of these theoretical foundations is informed by the person-based approach to intervention development[42,43]. We involved intended "end-users" extensively in our ADA[32] and we will extend this approach to the proposed project by involving NEET young women and mentors in identifying refinements following the feasibility trial. We will use a convergent design grounded in pragmatism[44] to integrate (within each trial stage respectively) data and analytic conclusions to assess points of convergence and divergence.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1. Primary and secondary objectives

Feasibility Stage:

There are two objectives for the feasibility stage: 1. test the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) to evaluate HOPEFUL, and 2. refine the RCT design. There are no hypotheses for the feasibility stage. Data will be collected on feasibility parameters to determine progression to the RCT.

Qualitative data collection will allow richer detail regarding participant perspectives on feasibility, accessibility, and acceptability; thus, enabling identification of any amendments needed to ensure the success of the RCT.

For Objective 1, We seek to assess if it is feasible to involve NEET young women and mentors in a randomised controlled trial of the HOPEFUL intervention (Research Question (RQ) 1.1). We seek to assess if it is feasible and acceptable to deliver HOPEFUL to NEET young women using a youth-initiated mentor model and whether NEET young women and mentors form positive mentoring relationships (RQ1.2). We seek to establish the acceptability of HOPEFUL and our research protocol from the experience of NEET young women and mentors (RQ1.3). For RQ1.1 and 1.2, data will be collected on the following feasibility outcomes and compared to the pre-specified progression criteria.

1. Number and proportion NEET young women identified, consented, eligible, and randomised by area per month, with number (%) youth-initiated mentors identified.
2. Number and proportion of scheduled HOPEFUL sessions completed by NEET young women.
3. Number and proportion of participants retained in the trial and completing 16-week assessments.
4. Data completeness for baseline and 16-week assessments.

Pre-specified progression criteria

Green	Amber	Red
Recruitment of 100% (n=70) of the target of NEET young women within the specified recruitment period	Recruitment of 50 to less than 100% (n=35-69) of the target of NEET young women within the specified recruitment period	Recruitment of less than 50% (n=<34) of the target of NEET young women within the specified recruitment period
At least 40% of young people identified during the recruitment process are eligible and interested in participation	30 to less than 40% of young people identified during the recruitment process are eligible and interested in participation	Less than 30% of young people identified during the recruitment process are eligible and interested in participation
At least 60% of NEET young women allocated to HOPEFUL complete 4 or more sessions	40 to less than 60% of young women allocated to HOPEFUL complete 4 or more sessions	Less than 40% of NEET young women allocated to HOPEFUL complete 4 or more sessions
At least 80% of participants provide primary outcome data at post-intervention assessment	50 to less than 80% of participants provide primary outcome data at post-intervention assessment	Less than 50% of participants provide primary outcome data at post-intervention assessment

If green criteria are met, progression to the definitive RCT will occur with no or minor changes, e.g., amending assessment order to maximise engagement. If amber criteria are met, progression to the definitive RCT will occur with non-substantial changes, e.g., amending entry criteria or intervention components. If the progression criteria are met with no major changes needed, then (with agreement from our TSC and DMEC committees), we will incorporate the feasibility stage into the definitive effectiveness trial. We will then reprofile the remaining sample size and duration of the full effectiveness trial accordingly. If neither green nor amber criteria are met, with the agreement of our Trial TSC and DMEC committees, the project will end at a standalone feasibility trial.

In the FT stage, we will additionally record the number and proportion of training and supervision sessions attended by mentors. We will additionally check the feasibility and acceptability of the RCT outcome data collection process (see below) as relevant to RQs 1.1 and 1.3. We will use outcome assessment and qualitative data collected in the feasibility stage of the trial to meet Objective 2. For Objective 2, we will use outcome assessment data to estimate the standard deviation of the Trait Hope Scale (primary outcome) in NEET young women (RQ2.1). We will use all data and consultation with oversight groups to inform answers to the minimum meaningful change in the Trait Hope Scale (RQ2.2) and any needed changes to intervention or research procedures (RQ2.3).

Randomised Controlled Trial Stage Hypotheses:

The primary hypothesis (H1) is that HOPEFUL with mentoring plus usual support services (HOPEFUL TOGETHER) will be superior to usual support services plus HOPEFUL workbook waitlist (HOPEFUL FUTURE) in increasing the primary outcome of hope at 16 weeks post-randomisation. The secondary hypotheses are as follows:

H2: HOPEFUL TOGETHER significantly improves the secondary outcomes of mental health symptoms, wellbeing, life meaning, time use, loneliness, and help-seeking for NEET young women at 16 weeks' post-randomisation relative to compared to HOPEFUL FUTURE.

H3: HOPEFUL TOGETHER (HOPEFUL and mentoring plus standard support) will be cost-effective compared to the HOPEFUL FUTURE in terms of improvements in hope and wellbeing.

H4: HOPEFUL TOGETHER significantly improves mental health symptoms, wellbeing, life meaning, time use, loneliness, and help-seeking for NEET young women at 12 months' post-randomisation relative to compared to HOPEFUL FUTURE.

H5: The mentoring relationship (measured post-intervention HOPEFUL session three) and idiographic goal attainment score (measured HOPEFUL module 6 or last provided) will mediate the intervention effects on primary and secondary outcomes at 16 weeks and 12 months post-randomisation.

H7: Change in hope at 16 weeks post-randomisation will mediate change in secondary outcomes at 12 months post-randomisation.

3.2. Primary and secondary endpoints:

The primary endpoint is 16 weeks post-randomisation and the secondary endpoint is 12 months post-randomisation.

3.3. Primary and secondary outcomes:

The primary outcome is hope, measured with the 12-item self-report Trait Hope Scale (THS)[23] at the primary endpoint of post-intervention (16-weeks). The secondary outcome measures are described below.

Wellbeing and mental health problem symptoms:

1. Wellbeing: 7-item Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS[45,46]).
2. Depression symptoms: 9-item self-report Patient Health Questionnaire (PHQ-9[47]).
3. Anxiety symptoms: 9-item self-report Generalised Anxiety Disorder Scale (GAD-7[48]).
4. Social anxiety symptoms: 12-item self-report[49] that combines Social Interaction Anxiety Scale short form (SIAS-6) and Social Phobia Scale short form (SPS-6).
5. Meaning in life: 10-item Meaning in Life self-report scale (MLQ[50]).

Social-occupational functioning:

6. Time spent in Education, Employment, and Training (EET), plus other constructive economic (childcare, housework, and chores) and structured (sports and structure leisure) activities: Time Use Survey (TUS) developed by the Office for National Statistics and adapted by our team for use with vulnerable people[51,52]. We will further adapt this measure to collect data on time spent preparing for EET (re-)engagement, e.g., looking for jobs, interview preparation. The TUS is a semi-structured interview, our team has also developed an online self-report version, allowing flexible means of data collection in this project.
7. Loneliness: using the short 8-item self-report UCLA Loneliness Scale (UCLA-8[53]).

8. Social and occupational functioning: assessor-rated using the Social and Occupational Functioning Scale (SOFAS[54])

Help-seeking:

9. 10-item self-report General Help-Seeking Questionnaire (GHSQ[55]).

Adverse Events

10. Modified Edinburgh Adverse Effects of Psychological Therapy Scale (EDAPTS[56]).

11. Adverse Events Checklist

Economics:

12. Formal and informal support and services: brief semi-structured Client Service Receipt Inventory (CSRI[57]) questionnaire, adapted to measure statutory and broader support.
13. Mental well-being adjusted life years: SWEMWBS[45] value set.

Proposed mechanisms of intervention effects:

14. Attainment for three personally identified goals: self-rated 3-item idiographic Goal-Based Outcome Tool (GBOT[58]) collected during intervention modules four to six.
15. Quality of mentoring relationship: short revised 12-item Working Alliance Inventory (WAI-SR[59]) completed by NEET young women and youth-initiated mentors (separately) after intervention session three.

Mentor outcomes:

16. Hope: 12-item self-report Trait Hope Scale (THS[23]).
17. Wellbeing: 7-item Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS[45,46]).

Outcome components for analysis:

The specific measurements will be total subscale or scale scores for all specified outcomes. Models will control for baseline values and will reflect mean values in each arm, unless otherwise specified, at the given endpoint. Additional details are given for the economic analysis.

Justification for outcomes:

Our ADA participants strongly advocated for hope as the primary outcome[32], and our previous systematic review[13] recommended measuring hope using the THS[23] in youth health research trials. We have implemented this preference in the proposed project, emphasising the following in support of this choice. First, hope is an important domain of mental health, which reflects "*a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community*" (World Health Organisation, 2023). Hope constitutes individuals' awareness of their goal-directed capabilities and underlies the ability to cope with life events, as well as predicting occupational and social functioning. Second, hope is a robust influence on different types of mental health symptoms and their impacts[13]. Third, hope is very sensitive to change; significantly increasing with even brief intervention in different populations and contexts[13]. Fourth, hope can be reliably measured using a short self-report scale[13,23]. Finally, our work with young people with mental health problems suggested increased hope is self-reinforcing[13] and is thus an especially efficient health intervention target.

We specified the secondary outcomes for the proposed project using 1) our ADA[32], in which NEET young women and practitioners identified relevant secondary outcomes and constructed a Theory of Change; and 2) our prior research[13] in which we created a process model of the effects of hope by collating scientific, practice-based, and lived experience evidence. We have chosen well-validated measures used successfully in our research[37,38] and in routine settings, with population norms, e.g., the TUS which is used by the Office for National Statistics[52], and the PHQ-9 and GAD-7 which reflect NHS entry criteria for Improving Access to Psychological Therapies (IAPT) services and are recommended as common metrics by the Wellcome Trust[60].

We will collect two outcome measures for mentors. These outcomes will not be tested as secondary outcomes of the HOPEFUL intervention as per outcomes for young women, and as such correspond to research questions 1.3 and 3.3 but do not correspond to any specific hypothesis. These outcomes will be tested as markers of the mentors' experience of being a mentor.

We hypothesise two mediators of intervention effects, mentor relationship quality and goal-based attainment, based on hope theory[41], that 1) the therapeutic relationship or alliance is an important non-specific vehicle for outcome gains, and 2) progress towards goals reciprocally reinforces hope[41]. Early alliance better predicts outcomes[61], thus we will aim to capture this after intervention session three. We also propose, as per our ADA[32] and prior review[13], that hope mediates change in secondary outcomes. We will use the qualitative process evaluation to triangulate inferences regarding proposed and any additional mechanisms of action.

4 TRIAL DESIGN

We propose an adaptive, assessor-blind, pragmatic, controlled superiority parallel arms randomised controlled trial. The trial will have two stages: a feasibility (FT) stage followed by a definitive RCT (referred to henceforth simply as "RCT") stage. The trial has two arms with 1:1 randomisation, stratified by local authority area and age. The two arms are 1. HOPEFUL with mentoring plus usual support (called HOPEFUL TOGETHER) *versus* 2. waitlist access to the HOPEFUL workbook plus usual support alone (called HOPEFUL FUTURE))

RCT outcomes are assessed at baseline, post-intervention (16 weeks; primary endpoint), and follow-up (12 months; secondary endpoint). Feasibility analysis will be done on two outcome assessment points, baseline and the primary endpoint of post-intervention (16 weeks). The adaptive component of this trial is that the feasibility stage will be subsumed into the definitive trial sample, unless feasibility results indicate this should not occur. Feasibility data will be used alongside pre-specified progression criteria to determine the appropriate continuation scenario as outlined. This is an adaptive approach for it uses the opportunity to reduce research waste and increase the efficiency with which results and impacts are generated without compromising the validity and the integrity of the trial. In practice, this means that research ethics and governance approvals are sought for one trial with two stages. FT stage participants will complete the 12-month assessment point and these data will be analysed as part of the RCT trial dataset, unless feasibility results indicate otherwise. The sample size for the RCT should therefore be interpreted as including 70 FT stage participants, unless otherwise indicated.

5 TRIAL SETTING

As per 2016 Department for Education guidance[62], local authorities have statutory duties to encourage, enable, and assist young people to participate in education, employment, or training. The goal is to prevent or shorten the time young people spend being NEET. The focus of commissioning for NEET young people is children's services, where case management is generally provided up to age 18 years. This increases to age 25 years for people with special educational needs, care leavers, and in some areas, mental health problems. Local authorities variably provide additional support for young people up to (typically) 25 years, including counselling, social support, and advocacy. Across England, voluntary and charity services (such as domestic abuse and substance use services) may also support NEET young people, e.g., through casework, mentoring, and counselling. These services may be fully or partly commissioned by local authorities.

The trial will run in Sussex, Kent and Norfolk, focusing on local authority areas containing a coastline or estuary as well as proximal local authority areas (i.e., within the same geographical county) that may not be directly situated on a coastline or estuary. This pragmatic definition reflects the fact that there is no established consensus for the term "coastal"[21] in public health, civic or demographic contexts. Authorities in Sussex, Kent and Norfolk report greater than the national average NEET population, as well as significant growth in local NEET populations since

2021[2]. We will concentrate recruitment on the neighbourhoods within the local authority areas that are within the two most deprived deciles according to current IMD data. However, we will not exclude any individual NEET young women on the basis of postcode alone, provided they reside in a local authority area in Sussex, Kent or Norfolk. This means that we will not exclude interested and otherwise eligible NEET young women from the research just because they happen to live within a non-deprived postcode within the geographical areas involved in the research.

6 SAMPLE

6.1 Eligibility criteria for young women

Inclusion criteria

1. Aged 16 to 25 years at time of consent
2. Identifying as a woman
3. NEET, operationalised as no involvement in education, employment, or training (EET) activity in past month as measured using the Time Use Survey – EET activity will not include informal activities such as casual babysitting, or one-off activities such as waiting tables at a single event
4. Resident in a local authority area in Sussex, Kent or Norfolk (consistent with definitions in "Trial Setting" at Section 5 above)
5. Able to give informed consent

Exclusion criteria

1. Current EET activity (including being on temporary leave from and with planned return to their place of employment/education/training)
2. Serious risk of suicide, operationalised as a score of non-zero on the suicidality item of the Patient Health Questionnaire plus a rating of four or more out of seven with respect to severity of the suicidality, as measured bv a screening version of Columbia-Suicide Severity Rating Scale (C-SSRS) [86].

6.2 Eligibility criteria for mentors

Inclusion criteria

1. Aged 18 years or more at time of consent
2. Able to give informed consent

6.3 Feasibility Stage Sample Size

The primary outcome is hope as measured with the 12-item self-report Trait Hope Scale (THS)[23] at the primary endpoint of post-intervention (16-weeks). To allow precise estimation of the SD of THS for checking the definitive RCT sample size, the FT sample size is 70, 35 per arm[63]. We will additionally collect qualitative interview data from approximately 10 NEET young women and 10 youth-initiated mentors. The qualitative sample size will be determined using the information power principle[64]; meaning that the number will be adjusted in relation to the richness and comprehensiveness of the obtained data.

6.4 Definitive RCT Stage Sample Size

A sample size of 248 (124 per arm) will provide 90% power for 5% significance, assuming a medium-small effect size of 0.4 for the primary outcome (16- week post-intervention hope) in an analysis of covariance (ANCOVA) with 20% attrition (estimated in line with our previous RCT with young people with social disability and mental health problems[38]) and a correlation of 0.5 between baseline follow-up outcome (the mean estimated correlation across

RCTs studied in the cited paper[65]). The sample size estimate for the main outcome analysis is sufficient for testing mediation[66].

The 0.4 effect size has been selected as a conservative estimate, with hope-focused interventions consistently achieving effects of this magnitude and greater in youth populations[13,67]. It equates to an increase of approximately 6 points on the THS or a change proportional to nearly 10% of the total possible scale range. This size effect is consistently associated with changes in mental health and social outcomes of a similar magnitude[13]. We will use the feasibility trial to sense-check this effect size by assessing the SD of THS and additionally by asking NEET young women to identify from their perspective the minimal meaningful change in hope. Whilst it is possible that an (upward or downward) adjustment could be needed to the sample size in virtue of these results, careful *a priori* covariate selection can increase the effective sample size at final analysis.

7 TRIAL PROCEDURES

7.1. Recruitment

Based on a previous RCT conducted with a similar group[38], we anticipate needing to assess for eligibility two to three times the number of NEET young women required to reach our target sample sizes (i.e., 140-210 for the feasibility stage and 496-744 for the definitive RCT), allowing for these samples to be separate should this be needed. We have specified the relevant feasibility outcome accordingly. We consider these numbers to be achievable based on population prevalence in the targeted geographies and our recruitment expertise and extensive links with the committed local authorities and voluntary and charity organisations.

Regarding population prevalence, local authorities are not statutorily required to monitor numbers of NEET young people aged 18 to 25 years. Yet this group have aged out of mandatory education and thus actually represent the majority (83.3%) of the total population of NEET young people[1]. Assuming that the known numbers of 16/17 year olds in each defined local authority area constitute 16.7%[1] of the total NEET population aged 16-25 and they have overall local NEET prevalence of approximately 13%, we anticipate the total 16 to 24 NEET young women population to be at least 15,000.

Our recruitment methods draw from approaches that we have used to recruit NEET young people in previous projects[37,38,68] and are guided by public involvement in the ADA[32] and generation of this protocol; with ongoing public involvement to responsively update these strategies. We will recruit NEET young women through local authorities, charities, and voluntary sector services focusing on provision across youth work, employability services, education, social care, care leavers, substance use, and non-NHS mental and sexual health services in the project areas. Local authorities and other youth support services in the respective areas are committed to this project and will respectively release their staff up to 0.4FTE in support of providing mentor supervision. Thus, these organisations also have a vested interest in supporting recruitment of young women such that mentoring is provided to them. We have engaged in addition with other relevant voluntary and charity organisations in and since the ADA. We will conduct scoping searches to identify relevant new services at project outset. We will work with the local services to create bespoke pathways to project involvement, including joining meetings between NEET young women and services in contact with them, asking services that hold locality databases of NEET young women to do mass mail-outs, and maintaining a regular physical researcher presence in service team meetings and within drop-in services. We will gift branded stationery (e.g., pens) to help services maintain project awareness. We will also invite NEET young women to self-refer, by promoting the project in relevant online and physical spaces, e.g., placing posters in service waiting rooms, libraries, and food banks. Participants will be encouraged to remain in the study with flexible and assertive strategies we have used previously[37,38,68], e.g., flexible meeting locations.

In addition, we will work with NHS primary care providers to promote the project via GP practices and community pharmacies. These organisations will act as Participant Identification Centres (PICs). We will ask these

organisations to display study posters in any waiting areas. We will also provide these organisations with flyers and ask them to share the flyers with any young women, who are potentially eligible, with whom they come into contact during usual clinical practice and remotely (e.g., by text message). This would include, for example, GPs and practice nurses offering routine appointments and specialist services such as sexual health clinics. We will work with primary care research delivery managers in the two relevant Local Clinical Research Networks (LCRNs; Kent, Surrey and Sussex and East of England) in order to engage these primary care PICs and support their involvement. In addition, we will work with these LCRNs to draw on any additional support they can provide with recruitment activities. The Clinical Research Network includes an agile research delivery workforce. Names for these teams differ regionally and may include Research Delivery Team or Direct Delivery Team. These teams comprise individuals, including research nurses, clinical research practitioners, and administrators, who focus on supporting health and care research on the NIHR portfolio that occurs outside of hospital settings. We will draw on all available support from these teams to support the work in each regional site to identify and recruit participants and/or to support research staff to do these activities. The activities that these teams do may thus involve supporting the recruitment activities outlined, including helping to identify organisations within which to promote the study and invite referrals, distribute promotional materials (including remotely), and support trial staff in meeting with prospective participants to describe the study and seek consent. We do not anticipate that members of these teams would meet, consent, or assess research participants in the absence of a member of trial staff, but rather that they might also be in attendance to support the work of trial staff in this regard. For example, we believe it is good practice for two members of staff to attend home and community visits with participants. The CRNs will transition to become Regional Research Delivery Networks from 1st October 2024. The names for these teams may change in line with this transition, but support for this aspect of research delivery will remain.

7.2. Participant identification

There are two identification/recruitment routes for NEET young women. The first is a professional referral and the second is a self-referral. In the first instance, a service provider (such as a local authority or charity) will identify the NEET young woman and offer to refer them into the project. Referring organisations will be encouraged to anonymously discuss prospective referrals with the research team if they are unsure about the potential for eligibility. Organisations will be explicitly instructed not to share personally identifiable information with the research team unless the young woman has verbally consented for them to do so. Organisations will be asked to discuss the project with prospective young women participants, using the project information sheets provided by the research team. The research team could join these initial discussions with the young woman, providing this was first offered by the referring organisation and the young woman gave verbal agreement. Otherwise, the referring organisation would, following verbal agreement to do so, pass the young woman's contact details to the research team. The service can use the referral form for this purpose. The second route is self-referral. In this route, a young woman would see a poster or flyer for the trial in a community venue or would be provided with information about the project by a referring service but without being directly referred. The promotional materials would invite the young woman to self-refer to the research team. The young woman (or someone on her behalf) would be able to do this by emailing the study team and/or by entering their name and a phone number and/or email address on the project website. The poster/flyer will contain a project email address and a QR code that will take the young woman to the project website.

At the point of receiving a referral via either route, the research team would contact the prospective young woman participant using the provided details and arrange a meeting to invite consent and complete the eligibility assessments. Data would be recorded on potential (anonymous data only) and actual referrals. Any reasons given as to a potential referral that did not result in an actual referral would be recorded, for example, where a prospective participant declined involvement and provided a reason.

7.3. Consent

The regional leads (Berry, Forbes, Wilson) retain overall responsibility for the conduct of the research in their region. The co-project leads take overall responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence. The co-project leads will work with the regional leads to ensure that all trial staff (Trial Manager (TM) and Research Assistant (RA)) with the delegated responsibility for inviting consent are appropriately trained and supervised according to the approved protocol and the Declaration of Helsinki. The TM and RAs will complete Good Clinical Practice training. Informed consent will be obtained prior to each participant undergoing research procedures.

Research consent will be invited from young women before the eligibility assessment. Research consent will also be sought from mentors. In both cases, an Informed Consent Form (ICF) will be used. The ICF will be used primarily digitally, but a paper version will be available for use as needed. Consent invited from young women will include a) consent to participate in the randomised controlled trial, and b) consent to participate in a qualitative interview about their experiences if they are invited to do so. The Participant Information Sheet (PIS) describes the adaptive design of the trial, such that participants will be aware that the trial will include a feasibility and definitive stage and that these could be decoupled if feasibility was not demonstrated. Should the feasibility stage identify any necessary amendments to this trial protocol that pertain to any changes to young women's consent, an appropriate amendment will be made to the PIS and ICF. Consent from mentors similarly covers a) consent to participate in the randomised controlled trial, involving the reporting of information regarding mentoring support they provide, and b) consent to participate in a qualitative interview about their experiences if they are invited. Young women's follow-up assessments occur after they have finished working with their mentors and mentors have no role in these follow-up assessments.

The process of taking consent will include the provision of information and a discussion with the prospective participant. The information will be emailed and/or posted to the prospective participant at least 24 hours before the meeting in the form of a PIS. We have created video versions of the PIS for young women and mentors that can be watched first. These videos contain abridged versions of the written material. The written version will be used in the consent meeting. The consent meeting will begin with a discussion between the potential participant and one or more members of the research team about the nature and objectives of the trial and possible risks associated with their participation. The prospective participant may invite another party to be present at this meeting should they wish to do so, for example, a parent or carer. The participant will be encouraged to ask questions about the trial and their potential involvement. The young women will be aged 16 years or over and thus can provide their own consent. For consent to be valid nonetheless, the individual must have the capacity to provide it. A capable person will understand the purpose and the nature of the research and its potential risks and benefits. They will be able to retain information long enough to make a decision about their consent, be capable of making that decision, and be able to do so freely. Whilst NEET young women are categorised as vulnerable, they are not considered to be at elevated risk of not having capacity to consent. All individuals should and will be assumed to have the capacity to make a decision unless evidence suggests that it is not present. For any young women who are referred by an organisation, a member of the research team will invite discussion about any concerns they have regarding the prospective participant's capacity for consent. For all prospective participants, research staff will be trained to identify evidence that capacity may not be present. This will involve asking prospective participants at the start of the consent meeting to explain what they have understood from the PIS. Next, the researcher will ask the prospective participant to explain what they think would happen if they consented to participate, followed by what they think would happen if they declined. Finally, the researcher would ask the prospective participant to identify what they think are the possible risks and benefits of being involved. This will enable the research team member to assess the prospective participant's understanding of the trial and their ability to retain information, understand the risks and benefits of participation, and make a decision regarding their involvement. This trial will not involve any participants, young women or mentors, who lack capacity to consent. If there is any concern regarding capacity for consent, the researcher will not invite consent at that time.

Prospective participants who do not wish to provide consent will be asked if they would like to provide any reasons for their decision. If they choose to do so, the reason(s) will be recorded. This will be done in a sensitive and gentle manner, with reassurance that they can provide reason(s) if they would like to but that there is no requirement to do so. The right of a prospective participant to decline participation without giving any reason will be respected. Moreover, the participant will be informed prior to providing consent that they remain free to withdraw at any time from the trial. This right to withdraw does not require them to provide any reason for discontinuation and will not have legal or medical consequences. The participant will be asked if they would like to provide any reason(s) for discontinuation. This will be done in a sensitive and gentle manner, with reassurance that they can provide reason(s) if they would like to do so but there is no requirement to do so. The right of a prospective participant to discontinue participation without giving any reason will be respected. It will be made clear to prospective participants in the PIS and ICF that data collected up to the point of withdrawal will be used after withdrawal. The participant will be informed that they can request the removal of their data up to when it is analysed. Aggregated categorised reasons for declined or discontinued involvement will be reported to the oversight committees, funder, and in the trial outcome paper. Categories will be broad with no risk of identifiability, for example "disinterested in the intervention". It is important that such data are recorded and communicated both within the trial and beyond to monitor accessibility, inform feasibility parameters, and provide relevant information for ongoing implementation considerations.

7.4. Eligibility assessment

Following consent, the researcher will invite the young woman to complete the eligibility assessment. At this point, the participant will be identified in electronic systems and on any physical paperwork using a local anonymous identifier (eligibility assessment ID). At this point, a participant details form will be completed to ensure that the project team has relevant contact details for the participant. The eligibility assessment involves three components:

1. Completion of demographic questionnaire to confirm the participant is aged 16 to 25 years and identifies as a young woman resident within a local authority in Sussex, Kent or Norfolk;
2. Completion of the Time Use Survey to establish NEET status
3. Completion of the Patient Health Questionnaire to establish presence of suicidality, followed by the Columbia-Suicide Severity Scale (C-SSRS)[86] to assess severity of suicidality if present.

The demographic questionnaire will be split into two parts such that the assessment does not end with final questions being about suicidality. The researcher will record assessment responses and then prepare an eligibility review form. The researcher will use this form to check eligibility with the TM (and/or regional lead and/or co-project leads, either if the TM is unavailable or if eligibility is unclear). The researcher will record and store the eligibility review form with the evidence of (in)eligibility, the decision, and name and authorisation (ink or electronic signature) of the person responsible for the decision. The form will be labelled using the local eligibility assessment ID and will not contain personal data nor personally identifying information.

The research team (RA and/or TM) will inform participants about their (in/)eligibility by telephone, unless this is not possible in which case they will email. Participants who are deemed ineligible at eligibility assessment will be able to be rescreened, unless the reason for ineligibility precludes this, for example, the participant is already aged over 25 years. Where relevant, the research team will re-invite the participant for re-eligibility assessment at the suitable time, for example, after the planned end of EET activity or after their 16th birthday if they are currently aged 15 years. Re-assessing for eligibility may be permitted up to the end of the recruitment period.

7.5. Baseline assessment

Following confirmation of eligibility, baseline data will be collected. Trial staff will aim to collect these data in-person, however, they can be collected flexibly via telephone or videocall if needed. The baseline assessments reflect the primary outcome (Trait Hope Scale; THS[23]) and all other secondary outcomes, except for the Time Use Survey (TUS[51,52]) and the Patient Health Questionnaire (PHQ-9[47]) that are collected during the eligibility assessment. In addition to the identified secondary outcomes, two very brief neurocognitive assessments will be completed at baseline. The purpose of these is to be able to describe and contextualise the trial sample. This is important with respect to the external validity of the trial and informing implementation considerations. These assessments are the Controlled Oral Word Association Test (COWAT[69]) for the letters F, A, and S, and the Morris Revision IV[70] of the Logical Memory Scale. The former tests verbal fluency and the latter verbal memory. Both can be scaled to population norms.

In addition to the collection of the baseline assessment data, the researcher will additionally engage the young woman in a short intervention designed to help them select an appropriate mentor. This intervention is described in detail in Section 8. The researcher will invite the young person to identify to them a potential mentor. This information will be recorded in the Trial Management File (TMF) for the use of the Trial Manager when they contact the young woman with the result of the randomisation. Following the completion of the baseline assessment and randomisation, the TM will contact the young woman by telephone to inform them of the randomisation outcome and then send a confirmation letter to the young woman and their GP.

7.6. The randomisation scheme and its implementation

Randomisation will be independently implemented by the Brighton & Sussex CTU. Randomisation will be stratified by relevant local authority area and age (16 to 18, 19 to 25 years) with permuted blocks of randomly varying lengths. Randomisation will use a 1:1 allocation ratio.

In practice, each randomisation will be requested through REDCap by local trial staff upon completing the baseline assessment. At the point of randomisation, a randomisation ID will be generated. This ID will comprise the local

authority area (e.g., BH for Brighton & Hove) and consecutive number randomised. The Trial Manager will inform each participant of the allocation to maintain outcome assessor blinding. This will be done via telephone and then confirmed via letter which will be copied to the GP and the referring organisation, if there is one.

7.7. Blinding

The trial is assessor blind. Trial participants will not be blind to intervention allocation. Outcome assessors (RAs) will be blind (masked) to intervention allocation. We will use well-tested means of ensuring blinding is maintained. Both blind trial staff (RAs) and non-blind staff (TM, peer researchers, TMG) will be instructed as to necessary procedures. These include prohibited discussions about RCT allocation, prohibited discussions about HOPEFUL intervention delivery, separate physical and electronic locations for storage of blinded materials (including blocked file access to allocation and intervention delivery logs), prohibition of blind and non-blind trial staff from working in close proximity to each other (e.g., within the same office), and consideration regarding the location of in-person meetings, telephone and videoconference appointments. We will also educate all groups involved in the trial (young women, mentors, any supervising and referring organisations) about blinding, why we use it, and how they can support the research team in maintaining it. It is not necessarily possible, however, to prevent all breaks to the blind. It may be, for example, that young women will accidentally break the blind within an assessment appointment. Wherever possible, the blind will be reinstated. This may involve different strategies, depending on the circumstances. For example, if the blind were to be broken before the participant provided follow-up data, we would try to arrange for the participant to be seen by another blind member of the research team or a colleague (for example, a Research Assistant on another project employed at one of the collaborating institutions who has sufficient experience, training, and meets any other access requirements (e.g. DBS or letter of access if needed)). Alternatively, we might invite the participant to complete their assessment as self-directed using the online self-report version. Should the blind be broken within an assessment meeting, an RA might conclude the meeting and arrange a follow-up with a blind member of staff and/or ask the participant to complete any remaining assessments independently. We would aim that any data thus far collected would be entered by a blind member of the trial team. Importantly, we would handle such situations sensitively, for example, ensuring as far as possible that participants experienced no distress or inconvenience as a result of the blind being broken. All such breaks to the blind will be recorded and reported transparently in the feasibility and main outcome papers for the trial. We would report breaks to the blind to the TSC and DMEC committees. We would not report blind breaks to the Research Ethics Committee (RGEC) for these do not reflect protocol deviations proper. This is because blinding is an aim and, whilst we will endeavour to reduce the risk of unblinding, this risk is never nil.

After completion of the final follow-up, to help preserve the blind, participants will be asked about intervention exposure to determine any presence and source(s) of contamination. Sources of potential contamination will be explored, e.g., asking those assigned to usual support only about intervention exposure, and to HOPEFUL about intervention sharing. We define contamination as access to the HOPEFUL intervention package, during the intervention delivery period, for those allocated to the usual support arm. This includes any exposure to intervention paper or digital materials and to being supported by a mentor trained and supervised in the HOPEFUL approach. This will be done using a short set of questions that participants answer via the REDCap system as self-reported data. A contamination flag would be added to participants as relevant, and a sensitivity analysis produced accordingly.

7.8. Peri-intervention assessments

Two assessments are collected during the intervention period, only for those in the HOPEFUL TOGETHER intervention arm. The first of these assessments is collected as part of the intervention package itself. This assessment is attainment for three personally identified goals. These data are collected using a self-rated 3-item idiographic Goal-Based Outcome Tool (GBOT[58]). This tool is part of the intervention and thus is completed by young women within modules four to six. Mentors will be asked to enter these data into the REDCap system as part of their adherence recording for sessions completed for modules four to six. The specific measurement will be the mean score for three priority goals from the module 6 GBOT. In the event of fewer than three identified goals or provided scores, a mean of the scores present will be taken. In the event of non-completion of the GBOT in module six, the GBOT score from module five will be used, or from module four if that is the only score present. The second assessment is the quality of the mentoring assessment as rated from the perspective of the young woman and the mentor. This will be measured using the short revised 12-item Working Alliance Inventory (WAI-SR[59]) completed by NEET young women and mentors (separately) approximately after intervention session three.

Both parties will be sent a link to this questionnaire for completion as a self-report online questionnaire after the third session of the intervention. The TM will monitor data completeness and will contact participants to offer support with completing this measure as needed, for example, reading the questions out and recording the responses into REDCap.

7.9. Intervention adherence

The assessment of intervention adherence pertains only to the HOPEFUL TOGETHER (HOPEFUL with mentor plus usual support) trial arm. Mentors will be asked to indicate the number of meetings they have with young women and will also be asked to indicate the modules and activities young women have completed. These data will allow us to describe how the intervention has been delivered and to identify young women who have received a "dose" of the intervention. A dose is defined as per the Theory of Change: at least four sessions, including one session each from modules 1, 2 and 4. Mentors may enter their data directly into REDCap or can otherwise be supported by the Trial Manager (TM) or other unblinded research staff to provide these data in a more accessible way. For example, mentors could provide data by phone to the TM, who can then enter the data into REDCap. Mentors will be asked to record, as part of these data, any costs incurred in using HOPEFUL. The latter data will be used in the health economic analysis. The TM or other unblinded research staff will monitor data completion on a regular basis and liaise with mentors to remind and/or support them to provide data. The TM will triangulate data on activities completed by asking young women in the intervention arm. This will be done when collecting the EDAPT (see below).

7.10. Follow-up assessments

Follow-up assessments are conducted at 16 weeks post-randomisation and 12 months post-randomisation. These assessments are identical. The assessments can be conducted via an individual link to a REDCAP survey, or, if preferred, conducted with the support of a researcher in-person, on the telephone, or via videocall. In the event that a young person is uncontactable, efforts to contact them and obtain follow-up data will continue periodically unless the young person express a wish to not complete that assessment or withdraw completely. Alternatively, efforts to obtain data will continue until trial end. It is likely that follow-up assessments can be conducted in one meeting (where applicable) but multiple meetings may be arranged if needed and/or the young woman prefers to have more shorter sessions. We will check for any updates to the Participant Details Form collected at baseline.

7.11. Mid-point contact

The TM or other unblinded researcher will contact all young women participants approximately halfway between their 16-week assessment and 12-month assessment due dates. The researcher will thank them for their trial participation, check on their contact details and communication preferences, and arrange the 12-month assessment date. The researcher will then send a letter confirming the arranged date for the 12-month assessment.

7.12. Adverse events

Adverse events will be elicited in both arms at the 16-week and 12-month follow up assessments using a self-reported Adverse Events Checklist that will be administered to participating NEET young women. In addition, potential adverse psychological effects arising directly from participation in the intervention arm will be elicited by an unblinded researcher in a telephone/video call using the modified Edinburgh Adverse Effects of Psychological Therapy Scale[56] (EDAPTS). The EDAPTS will be administered shortly after the 16-week and 12-month follow-ups. The EDAPTS was adapted through review with the PIP prior to research ethics approval to ensure it captures important adverse effects relevant to our target population. The TM or other unblinded researcher will additionally ask the mentors to complete the same scale shortly after the young woman's 16-week assessment, i.e., at the end of the intervention period, in their own 16-week questionnaire as described below. Further, AEs may also be detected spontaneously via verbal report from young women participants or mentors during any contact with researchers. The full procedure for detecting and subsequent reporting of adverse events is described in Section 11.

7.13. Mentor baseline and 16-week questionnaires

Mentors will complete two short self-report questionnaires at baseline and 16-week follow-up. These questionnaires are the Trait Hope Scale (THS[23]) and the Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS[45,46]). The baseline data will be collected during the mentor consent meeting. The 16-week follow-up data will be collected remotely (telephone or videocall) by the TM and/or RCP. The 16-week data collection will additionally include the EDAPTS[56], as described above.

7.14. Qualitative data

Trained employed peer researchers, who are young women with experience of being NEET, and the TM and RCP will collect qualitative data. They will not be blind to allocation, for interview content (feasibility stage) or completion (definitive RCT stage) will vary by arm. The data will be collected using semi-structured interview guides co-designed with our PIP appropriately for each stage and arm. Data will be collected online, by telephone, or in-person, depending on participant preference, location, and safety considerations. Interviews will be securely recorded and transcribed with identifying information redacted.

In the feasibility stage, we will use a similar approach as to our previous trials[71,72]. Qualitative data will be collected on acceptability parameters[73], e.g., intervention coherence and burden. Data will also be collected on general reflections regarding research participation, including research process and intervention experience, barriers to engagement, and intervention accessibility and feasibility. In the definitive RCT stage, qualitative process evaluation data will be collected as per MRC guidance[40], and as informed by the intervention Theory of Change to explore understanding of, and interactions with, the intervention; mechanisms and contextual moderators; and any unintended outcomes. We will use the qualitative process evaluation to triangulate inferences regarding proposed and any additional mechanisms of action.

7.10. Reimbursement/payment

Reimbursement will be offered to NEET young women research participants for their involvement in research assessments and qualitative interviews. They will be offered a £20 shopping voucher after completing each assessment point and a £20 shopping voucher for completing a qualitative interview. Mentors will be offered a £20 shopping voucher for completing a qualitative interview. Public involvement colleagues (PIP, public TSC members and peer researchers) will be paid for the time they work at the rate of £25 per hour.

7.11. Schedule of procedures

Procedures	**Visits/ Assessment points**				
	Consent/ Eligibility	**Baseline**	**Intervention**	**16 Week Follow Up**	**12 Month Follow Up**
Informed consent	X				
Eligibility (screening) assessment (listed in order of completion)					
Demographics part one	X				
Time Use Survey (TUS)	X			X	X
Patient Health Questionnaire (PHQ-9)	X			X	X
Demographics part two					
Baseline assessment (listed in order of completion)					

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Procedures	Visits/ Assessment points				
	Consent/ Eligibility	**Baseline**	**Intervention**	**16 Week Follow Up**	**12 Month Follow Up**
Trait Hope Scale (THS)		X (Young women and mentors)		X (Young women and mentors)	X
Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)		X (Young women and mentors)		X (Young women and mentors)	X
Generalised Anxiety Disorder Scale (GAD-7)		X		X	X
UCLA Loneliness Scale (UCLA-8)		X		X	X
General Help-Seeking Questionnaire (GHSQ)		X		X	X
Morris IV revision of logical memory test		X			
Meaning in Life self-report scale (MLQ)		X		X	X
Controlled Oral Word Association Test (COWAT)		X			
Combined Social Interaction Anxiety Scale short form (SIAS-6) and Social Phobia Scale short form (SPS-6)		X		X	X
Social and Occupational Functioning Scale (SOFAS)		X		X	X
Client Service Receipt Inventory (CSRI)		X		X	X
Randomisation		X			
Peri-intervention assessments					
Working Alliance Inventory- Short Revised (WAI-SR)			HOPEFUL TOGETHER ONLY, c. intervention session 3, completed by young women and mentors		

Procedures	Visits/ Assessment points				
	Consent/ Eligibility	**Baseline**	**Intervention**	**16 Week Follow Up**	**12 Month Follow Up**
Goal-Based Outcome Tool (GBOT)			HOPEFUL TOGETHER ONLY		
Adherence data			HOPEFUL TOGETHER ONLY, completed by mentors		
Adverse events/effects					
Adverse Events Checklist				X	X
Modified Edinburgh Adverse Effects of Psychological Therapy Scale (EDAPTS)				Completed by young women and mentors	Completed by young women
Routine monitoring of adverse events	By researchers/mentor supervisors based on participant contacts	By researchers/mentor supervisors based on participant contacts	By researchers/ mentor supervisors based on participant contacts	By researchers /mentor supervisors based on participant contacts	By researchers /mentor supervisors based on participant contacts
Qualitative interview				Completed by a subset of young women and mentors	Completed by a subset of young women and mentors

Note: Assessments completed by (or assessor-rated in relation to) young women unless otherwise specified.

7.12. End of study

The end of study is defined as three months after the last participant visit in any project locality. See Section 18 for the project Gantt chart.

8 TRIAL ARMS

8.1 HOPEFUL TOGETHER (Intervention)

The package of materials is called HOPEFUL. The trial intervention arm comprises the use of the HOPEFUL package with support from a youth-initiated mentor; referred to as HOPEFUL TOGETHER.

Intervention components

HOPEFUL is a six-module psychosocial intervention comprising psychoeducation, cognitive, behavioural, and interpersonal activities. HOPEFUL is designed to be supported by a youth-initiated mentor. The intervention is outlined here using TiDIER descriptors[74] and the intervention Theory of Change. Further details are provided regarding the intervention materials, mentor selection, and mentor supervision.

- WHY: The explicit primary focus of HOPEFUL is on hope, drawing primarily on cognitive hope theory[41]. Changes are expected in mental health and socio-occupational outcomes (including engagement in education, employment, and training (EET)). However, the primary focus is on hope, for NEET young women emphasised this is a more novel, engaging, sensitive, and relevant explicit key intervention target than mental health and EET outcomes.
- WHAT: The intervention is designed with inclusive entry criteria in mind for NEET young women. The intervention is delivered primarily 1:1 and in-person, supported by an accessible (non-patronising) online/paper workbook. The intervention comprises six modules, each of which contains core psychoeducational material and a menu of selectable activities to put newly learned concepts and skills into practice. The intervention could be delivered using formal or informal group-based approaches if wanted.
- WHERE: The intervention has been designed to be accessed through multiple services and routes. The intervention has been designed to be delivered primary in in-person meetings situated in non-stigmatising community locations. There is in-built encouragement in both young women's and mentor's materials to complete activities in wanted in appropriate outdoor places to increase physical activity and nature exposure, e.g., walking discussions with mentors.
- WHEN AND HOW MUCH: The intervention has been designed to be delivered over a flexible and collaboratively agreed session number and spacing, with guidance of 4-12 sessions of 30-90 minutes each, spaced 3-14 days apart, over 4-12 weeks. A full dose is defined (as per the Theory of Change) as at least 4 sessions, with at least one each from modules 1, 2, and 4.
- TAILORING: Initial engagement with the young woman should involve a collaborative discussion around preferences and boundaries. Sessions can be delivered in-person, online, and/or via telephone as preferred. Module activities can be completed flexibly using role play, discussions, creative arts, writing, outdoor activities, and/or in self-study.
- WHO PROVIDES: The intervention is designed to be supported by a youth-initiated mentor, i.e., someone known to and trusted by NEET young women. The mentor should be hopeful, encouraging, understanding, youth-centred, consistent, and non-patronising. The mentor's role is to provide supportive accountability, i.e., to provide encouragement to the NEET young woman to continue using the package and to offer assistance to understand the components when needed. The mentor does not need to have or use specialist knowledge or technical skills. The mentor is provided with brief, self-administered written and video-based training on hope, intervention model and components, and principles of providing supportive competency (with in-built self-rated competency tests), supervision (c. fortnightly), and a paper/digital intervention manual.

Intervention materials

The intervention comprises six modules. Before engaging with the modules, there is an introductory component in which the young woman and mentor discuss their mentoring relationship and agree a set of guidelines for this practice. The intervention is introduced. The mentor will support the young woman to identify expectations and any concerns and establish some general preferences about how to use the intervention. The six modules are then designed to be used in sequence, although they are standalone such that young women could choose to skip a module if they did not want to complete it. The first module (About Me) focuses on building sense of self, and increasing time spent in meaningful activity. Explicit targeting of hope as a changeable mindset is gently introduced in Module 2 (About Hope). This module focuses on exploring young women's own sense of hope and its sources. Modules 3 to 6 (My Values, My Goals, My Hope Network, Staying Hopeful) focus on learning and practising skills for identifying, setting, and pursuing goals, and overcoming barriers. Each module has a core psychoeducational component and a lived experienced story from a young person relevant to that module focus. Both are presented in animated video format. Each module then provides a menu of selectable session activities to practise key skills according to personally tailored preferences, and optional takeaway activities for self-completion. The activities are provided in the form of individual worksheets that contain instructions for completion. The activities have been designed to be simple to understand and to allow for creativity and flexibility in their completion, for example, using writing, drawing, collaging, discussions, and role play. Each module contains a "share sheet". This sheet can be used to share the focus of that module with anyone that the young woman would find it helpful to do so and ask for their support in using the skills learned in daily life if wanted.

Young women randomised to the HOPEFUL TOGETHER arm of the trial will be offered a paper-based version of the workbook. They will additionally be sent a link to set up an account on the intervention website on which they can access these materials in a digital form. Mentors will be offered a paper-based version of the mentor manual and will also be sent a link to set up an intervention website account. They will be able to access training videos in addition to digital versions of the mentor manual. The intervention will be protected from access outside of the trial for the duration of the trial. To set up an account, participants will need to enter only minimal information i.e., their name and email address. This information will be stored securely and not shared. The website is being developed by We Are Herd (https://weareherd.co.uk/), an experienced developer in the creation of websites for the purposes of health intervention research.

Mentor selection

After establishing eligibility and as part of the baseline assessment, Research Assistants (RAs) will present a brief video intervention about how to select an appropriate mentor. The video intervention includes:

- The described characteristics of an appropriate mentor as hopeful, encouraging, understanding, youth-centred, consistent, and non-patronising; explaining what these terms mean and why they are likely to be helpful mentor characteristics.
- That the mentor would ideally have the availability to see the young person on about a weekly basis, that ideally these meetings would be in-person, but that it would be helpful if the mentor were flexible and could meet by phone and/or videocall if required.
- That the mentor would need to have some brief training and then would have regular supervision from someone in a local authority or a local charity.
- The circumstances and characteristics that reflect someone who is not an appropriate mentor – emphasising that the mentor should not be anyone with whom the young woman has a relationship that they might describe as negative, confusing, uncertain, complicated, worrying, or argumentative. The video will emphasise that anyone who the young woman felt was critical, controlling, hostile, or potentially abusive in any way, would not make a good mentor.
- The video will advise that a parent would not normally be recommended as a mentor.

The RA would check the young woman's understanding of the video and their reflections. The RA would then talk to NEET young women to suggest a preferred mentor and also a "back-up" should the first person become unavailable. The RA would check key details about the identified preferred mentor, i.e., that the young woman describes the prospective mentor as having the characteristics of an appropriate mentor and that the individual would be perceived to be willing and available. The RA will ask the young women whether the relationship is positive and supportive. The RA will check explicitly that the relationship is not characterised by any possible abuse, risk, or other potential safeguarding issues.

At the point of randomisation, the Trial Manager (TM) will confirm the preferred mentor with each young woman allocated to HOPEFUL TOGETHER. The TM will send a mentor information sheet to the young person and establish what, if any conversations, the young woman had had with their preferred mentor. The TM will ask the young person to provide a means to contact the prospective mentor. The TM will encourage the young woman to send on the mentor information sheet and invite this individual to be their HOPEFUL mentor if possible, and/or the TM could discuss the mentoring opportunity directly with the prospective mentor if preferred by the young person. The TM will re-contact the young woman shortly after to discuss the mentor's response. Should the preferred mentor be unable to take up the invitation, the TM will work with the young woman to identify another preferred mentor. If the young woman was unable to identify another mentor or the next identified person did not agree, the TM will identify a professional who will be able to take this role. This will be done on a case-by-case basis, considering the young woman's address and preferences. When a mentor was identified and they agreed to take up this role, they will be asked to complete an online consent form with the support of the TM.

Should a mentor begin to support the young woman and then drop out, we will manage this on a case-by-case basis. We will consider how long remains in the intervention period and we will engage with the young woman to understand their preferences regarding a new mentor. Assuming the young woman agrees (and they are not already very close to the end of the intervention period), we would invite the suggested "back-up" mentor to take over. If this was not possible, we would ask if the mentor supervisor to use the time they otherwise would have used for providing supervision to check-in directly with the young woman.

Mentor training and supervision

Mentor training will be primarily self-administered using standard online resources accessible through the project website (i.e., video training, written manual, and self-rated competence tests), and also include a 1:1 videocall with a clinically qualified senior researcher. The self-administered video training will include role plays to help the mentors to feel knowledgeable and confident about how to support young women to use the HOPEFUL workbook. Mentors will also be offered a paper-based mentor manual. The manual will contain information about HOPEFUL, the principles of HOPEFUL mentoring, trouble-shooting guidance, and further informational resources that can be used or provided to the young woman at individual need. The purpose of the 1:1 videocall is to review the training content, address questions, and discuss next steps required to begin the mentoring process.

The identified mentor will be linked with a supervisor. The supervisor will be selected from a local authority or charity involved in the project. We will conduct mentor supervisor training online and invite as many prospective mentor supervisors from relevant organisations as can attend to enhance the available pool. The TM will identify a prospective supervisor for each mentor, with support from the co-leads and/or regional site leads. The selection will be based on supervisor capacity, for which the TM will keep an ongoing log of mentor supervisee caseloads per supervisor. The supervisor will confirm they can take on the mentor's supervisor and, if not, another mentor will be sought. The mentor supervisor will be provided with the contact details for the mentor and be asked to get in touch and arrange the first supervision meeting as soon as is possible. We have secured agreement for mentor supervision from local authorities and voluntary and charity organisations (Letters of Support) with a high level of interest. Local authorities and charities will retain the right to set parameters around mentors they will not agree to supervise, for example, on the basis of the age or location of the young women being mentored. To date, all organisations providing mentoring support have agreed to supervise mentors of young women up to and including age 25 years. Should there be any unexpected delays in setting up mentoring supervision in any regional site, mentor supervision could be supplemented by the KCL-based Research Clinical Psychologist (RCP) employed within the research team.

Supervisors will be offered brief training that will be online and accessible through the project website. This training will cover information about HOPEFUL, the mentor's role, and recommendations for supervision frequency and focus. Supervision will be provided approximately fortnightly, with flexibility to offer it more or less frequently as agreed between supervisor and supervisee. Supervision will likely be via telephone or videoconferencing but could be in person if possible and preferred. Mentor supervisors will receive training and brief guidance from the research team, plus access to the intervention materials and mentor training for their reference. All organisations offering supervision are experienced in supporting this group of young people and in offering support and intervention focused on their wider family and social networks. Supervision will use the model that organisations already use as part of their organisational approach. This model is broadly a non-hierarchical supportive youth supervision model. Typically, this model is done on a one-to-one basis with one supervisor and one supervisee, however, group supervision may also be used. Supervision will focus on both the mentor's wellbeing and on their reflections on their mentoring practice. The supervisor will help the mentor to notice and celebrate positive aspects as well as identifying challenges. The supervisor will remind the mentor to make use of their intervention manual and the "trouble-shooting" guidance provided within. The TM and/or RCP will offer mentor supervisors a regular teleconference to enable supervisor peer support and reflective practice, to provide additional bespoke guidance as needed, and to discuss and resolve any trial-related issues.

HOPEFUL Theory of Change Model

Problem: Young women who are Not in Education, Employment and Training (NEET) lack hopefulness and are at risk of potentially long-term mental health problems and social exclusion

Focus: Enhancing hopefulness through a structured psychosocial intervention, delivered using online and printed materials with 1:1 support from a youth-initiated mentor

Inputs	**Outputs**			**Outcomes**				
	Participation	**Activities**	**Change in outcome category facilitated by (module)**	**Mechanisms of outcome**	**Category**	**Short-term (0 to 6 months)**	**Medium-term (>6 to 12 months)**	**Long-term (>12 months to 5 years)**
People and services ● Mentors ● Mentor trainers/ supervisors ● Referrals initiated by relevant statutory and community and voluntary sector organisations and/or directly from NEET young women **Resources and materials** ● Workbook (online/paper) for young woman, presenting six modules; each focusing on a specific topic related to hope and containing a menu of activities ● Training resources, supervision,	● Young women who are NEET and living in deprived coastal communities ● Youth-initiated mentor for each young woman (or alternative mentor identified if needed)	**HOPEFUL intervention delivery** ● 1:1 psychosocial support, guided by a mentor, according to a structured but flexible manualised programme ● Active encouragement to spend time outside of the home (e.g., walking conversations; activity scheduling) ● Completion of workbook by young person ● Group component possible, e.g., toward end of the intervention ● Basic needs identified and addressed **Training and**	● Hopeful mentoring relationship (1-6) ● Activity scheduling (1-6) ● Learning about hope and its sources (2) ● Imagining positive future self (3) ● Practising skills in goal setting and pursuit (4) ● Increasing positive social relationships (5)	● Personal goal attainment, Goal-Based Outcome Tool ● Quality of mentoring relationship, Working Alliance Inventory	**Hope**	● Improved motivation[a] ● Recognise the importance of setting achievable goals[a] ● Improved confidence to change behaviour[a] ● Ability to set realistic goals and develop plans[a]	● Raised life aspirations	● Sustained increase in hope[a] ● Sustained raised life aspirations
			● Boosting time spent in activities outside the home (1-6) ● Addressing basic needs, e.g., sleep (1) ● Identifying interests and strengths (1) ● Change in mental health and well-being is additionally facilitated by the outcome of increased hope		**Mental health and wellbeing**	● Increased self-awareness and ability to reflect[b] ● Improved sense of identity	● Reduced anxiety[c] ● Reduced depression[d] ● Reduced suicidality[d] ● Decreased mental health support needs[c,d,e]	● Improved resilience ● Reduced alcohol and substance misuse ● Reduced contact with youth custody/ criminal justice orders[e] ● Decreased mental health service use, including A&E[e]
			● Hopeful mentoring relationship (1-6) ● Identifying interests, strengths and values (1, 3) ● Imagining positive future self (3) ● Practising skills in goal setting and pursuit (4) ● Increasing social capital via social relationships (5) ● Change in EET is additionally facilitated by increased hope		**Employment, education and training (EET)**	● Improved capability (skills and interests)	● Increased awareness of careers and access routes ● Entered EET[f]	● Maintaining meaningful EET[f] ● Motivation to upskill, seek promotions and continue to develop
			● Positive and consistent mentoring relationship, and any group activities (1-6) ● Practising communication skills (5)		**Social functioning**	● Improved social skills ● Increased opportunities to form meaningful friendships[g]	● Increased network of support and positive relationships	● Improvement in parenting skills

and manual for mentors		**supervision** ● Provided to mentors using scalable formats (e.g., video-based training; group supervision) that and proportionate to intervention requirements	● Understanding characteristics of hopeful relationships (5) ● Change in social functioning additionally facilitated by increased hope			● Increased levels of trust in social relationships ● Expanded social networks and support systems[g]	with other people[g]	
			● Supportive relational environment through mentor (1-6) ● Increasing positive social relationships (5) ● Practising communication skills (5) ● Change in help-seeking outcomes additionally facilitated by increased hopefulness		**Help-seeking**	● Improved knowledge of available support and how to access it[h]	● Confidence to seek and ask for the right type of support[h]	● Sustained confidence to seek and ask for the right type of support[h]
Assumptions: Capacity in existing services to train/supervise mentors; HOPEFUL intervention is viewed by stakeholders as an acceptable and feasible intervention; Intervention dose = 4 sessions (a session constitutes a minimum completion of one core and one selectable/takeaway activity), including at least one session each from modules 1, 2, and 4.								
As measured by: [a]Trait Hope Scale; [b]Short Warwick-Edinburgh Mental Well-Being Scale; [c]Patient Health Questionnaire; [d]Generalised Anxiety Disorder Scale; [e]Client Service Receipt Inventory; [f]Time Use Survey; [g]UCLA Loneliness Scale; [h]General Help-Seeking Questionnaire,								

8.2 HOPEFUL FUTURE (Comparator)

The comparator is usual support plus waitlist access to the HOPEFUL workbook for self-directed use. This arm is called HOPEFUL FUTURE. Following our experience in a previous RCT[38] involving young people with social disability and mental health problems, we anticipate that usual support will vary from nothing to support from social services, educational or employment services, and/or specialist mental health services. We aim to standardise this support by offering NEET young women a best practice support guide at allocation with information about local relevant provision. This will also refer to the option of seeking informal support from a putative mentor if they wish. Data will be collected on usual support provision (form, frequency/duration), financial benefits, and informal/family support using the Client Service Receipt Inventory (CSRI[57]).

At the end of their trial involvement (i.e., after their 12-month assessment and any subsequent qualitative interview to which they are invited), we will offer access to the HOPEFUL workbook to these participants for use however they choose. We will make no restriction as to whether young women could identify and request support from a mentor to use the intervention if they wanted to do so. However, the research team will not provide any support to identify or involve a mentor.

12.3. Assessment of adherence with intervention

Intervention adherence will be monitored in the intervention arm. Intervention adherence data will be sought from mentors to assess fidelity of delivery and determine dose. These data will be collected using REDCap to record numbers of sessions offered and taken up and their modes (i.e., in-person, phone, videocall), and progress through modules. Specific components delivered will be recorded using a module-specific checklist on REDCap. In addition, mentor supervisors will report on the number, duration, and mode (individual versus group) of supervision sessions mentors attend and the number of supervision sessions offered.

In the comparator arm, whilst adherence will not be monitored, data on usual support service use will be collected. These data will be used for the economic analysis and will be used descriptively to identify the usual support services used by participants in the comparator and intervention arms. The use of the HOPEFUL workbook of materials, provided to comparator arm participants at the end of the trial, will not be actively monitored.

8.4. Post trial care

We will not provide post-trial care. Trial participants, of either arm, will be able to retain their copy of the HOPEFUL workbook for future reference. Mentors will be able to retain their mentors' manual. Unless we generate evidence of harm, the HOPEFUL intervention will be made publicly available and thus will be accessible to trial participants by this means in addition. For HOPEFUL TOGETHER participants, the presence and nature of ongoing contact between mentor and mentee is explicitly discussed at minimum at the beginning and end of using the intervention. Any ongoing contact is at individual discretion. Mentor supervision will include focus on issues related to the nature of ongoing contact. Those individuals and services involved in the provision of mentor supervision are not mandated by the research team to provide ongoing supervision to trial mentors, nor other mentors. However, these organisations have expressed a commitment to providing this mentoring on an ongoing basis in their local area, assuming effectiveness. In addition, we aim as a trial team will encourage the ongoing implementation of this mentor supervision, assuming intervention effectiveness. We plan to use multiple implementation strategies to encourage this practice. We aim, in addition, to use these strategies to encourage new uptake (assuming effectiveness) in regions not involved in the trial programme.

It is possible that support services (statutory, voluntary and community) could become newly involved in the care of young women participants due to their trial participation. For example, young women who have a mentor, who themself receives supervision, could be signposted or referred to support services in response to an unmet need, or young women in the waitlist arm could use the information we provide about local provision to access new support. In any of these cases, the provision of ongoing support will always be at the discretion of the respective organisation(s).

9 PROJECT MANAGEMENT

Berry and Michelson will provide shared scientific leadership of the project. They will draw from substantial expertise and experience developed as a Trial Managers, investigators, and oversight committee members of large, multi-site RCTs. These include trials of an equivalent complexity and with very similar populations. Berry will additionally lead on operational delivery, supervising the Trial Manager (TM) and working closely with the Brighton and Sussex CTU to oversee recruitment, randomisation, data collection and management, and data analysis. Michelson will oversee intervention quality assurance and update intervention materials between the two trial stages (if needed), supported by a Research Clinical Psychologist at KCL. Data analysis will be led by Bremner (statistical), McCrone (economic), and Berry and Michelson (qualitative and adherence).

One research assistant and one peer researcher will be employed respectively at three institutions: University of Sussex (co-ordinating recruitment and data collection in relevant settings across Sussex); University of Kent (co-ordinating in relevant settings across Kent); and Norfolk & Suffolk NHS Foundation Trust (co-ordinating in relevant settings across Norfolk). The TM will direct these staff, and will monitor recruitment, assessment and qualitative data collection, intervention and assessment retention, with support from area leads Berry (Sussex), Forbes (Kent), and Wilson (Norfolk). Monthly whole research team progress meetings will be held, with smaller weekly delivery meetings between the TM, local research staff, and area leads as needed. The TM and/or RCP will facilitate a 4 to 6-weekly meeting with all mentor supervisors to monitor delivery and create a peer group for sharing supervision practice. The Chief Investigator, the TM, and the RCP will work with the web designer to ensure the mentor and supervisor intervention and training materials are accessible, develop the intervention checklists and work with the CTU to set-up adherence data collection processes, support the co-development of qualitative interview guide components that focus on capturing intervention acceptability and data relevant to the Theory of Change, and enact any changes needed to intervention materials as indicated by the feasibility stage.

Fountain reprises her ADA role as public involvement lead. She will supervise the PIP co-ordinator and, with support from the TM, lead the recruitment and training of peer researchers and will offer supervision relevant to the lived experience aspects of their roles. Training will include research methods, interviewing techniques, and thematic analysis, with additional training identified using individual training needs analysis. Yearly in-person research team meetings will be held for the purpose of maintaining team cohesion and providing any necessary refresher training.

10 EQUALITY AND INCLUSIVITY

Our group has long focused on the needs of the most vulnerable young people in society, who, alongside difficulties in accessing adequate support, are often excluded from research too. Such exclusions are typically accidental (e.g., research is inadequately promoted to marginalised young people) and/or pragmatic (e.g., lack of staff resource to hold assessment meetings where young people feel safe and comfortable, such as within their own homes). We will work in line with the NIHR Equality, Diversity, and Inclusion (EDI) strategy[75] to embed diversity and inclusion considerations throughout our proposed project as follows:

1. INCLUSIVE ENTRY CRITERIA: We propose minimal exclusion criteria. We include a large age range of 16-25 years, define “coastal” and “deprived” inclusively, with “woman” defined by self-identification.
2. STUDY PROMOTION: We will widely promote the study through a range of channels to ensure reach and diversity in participation, including prior Application Development Award (ADA) networks, contacts from recent and ongoing research studies (e.g., the NIHR ARC-KSS funded CATALYST youth mental health service adaptation project in which Berry and Michelson are co-investigators), and those newly identified in scoping searches. We will promote the project in multiple ways considering people who struggle to physically attend community venues and those who face digital exclusion, i.e., using physical (e.g., posters) and social media advertisements, and engage professionals and volunteers in word-of-mouth promotion. We will also target families as they are often the vehicle for help-seeking[31]. We will work closely with the PIP to identify barriers relevant to EDI and refine our promotional strategies accordingly. We will translate digital and printed recruitment flyers into the five most spoken languages other than English across the project areas. We have produced easy read versions of the Participant Information Sheets and video versions too to enhance accessibility of information for prospective participants.

3. SETTING: There is a national lack of service provision for NEET young women outside the remit of children's services. Most NEET provision is nationally commissioned without assessing local contexts or considering the needs of "transition-aged youth" bridging late adolescence to early adulthood. We will work closely with local partners representing youth employment, education, health, and social services with experience of our target population to advise on suitable methods of recruitment, engagement, and mentor supervision provision for NEET young women including those aged 19 years and over. We aim to invite a small number of such professionals (mindful of need for independence) to the TSC and engage with others as part of project set-up and the maintenance of recruitment pathways. We will also work with the PIP to refine engagement strategies considering age subgroups. We will additionally conduct an age-based subgroup analysis.
4. PARTICIPANT INVOLVEMENT: We will use flexible and gentle yet assertive methods to enhance the inclusivity of trial recruitment and facilitate ongoing engagement developed through previous projects. We will offer participants: meetings in non-stigmatising places including home visits (e.g., for young parents); data collection in-person, by phone/ videoconferencing, or online self-report, thus accessible to people who prefer remote involvement and/or leave the project area during follow-up; presence of supportive persons in attendance where wanted; translation and interpretation services for project materials and meetings.
5. PUBLIC INVOLVEMENT: We will offer the same flexibility to public involvement colleagues and peer researchers, and fund laptops and mobile phones for peer researchers to ensure the posts are accessible.
6. EVALUATION: We will attempt to record instances of disinterest or ineligibility, and intervention and research discontinuation. Qualitative interviews will explore participant experiences to identify issues in accessibility and acceptability, and any other barriers to inclusion, feasibility, and effectiveness. We will sensitively collect and report EDI data (including ethnicity, sexuality, presence of mental health problems and disability) to monitor the reach of our research, and to identify our sample with respect to their diversity and representativeness of the NEET young women population. We will report the results of the age-based subgroup analysis. We will host translated versions (in England's five most spoken languages) of the project infographics and videos on our project website to increase accessibility of project outputs.

11 RISK AND ADVERSE EVENTS

11.1. Assessment and management of risk

The present trial is categorised as presenting no higher risk than that of usual care. The ongoing crisis in youth service provision is such that the majority of their care is provided by relatives and friends. The current programme of work seeks to harness an opportunity to help these individuals to support these young people better. We seek to provide them with a theoretically derived package of intervention materials that have been developed with and for young women and their mentors. This package of materials has been assessed by young people and practitioners are being accessible. Moreover, the focus of the package is positive, i.e., it seeks to support young women to develop and pursue future aspirations, to become more confident, to be more aware of their strengths and capabilities, and to engage in increased amounts of positive and meaningful activity. In addition, we seek to provide the people that already support these young women with resources to do this more effectively and with more confidence. Through a mentor manual and training package, these individuals will be able to enhance their confidence and competence in having sensitive and validating conversations with these young women. Through these resources, these individuals will be better equipped to help young women to thrive. Finally, we seek to provide these mentors with access to supervision from within their local authority and/or relevant local charity. Through doing so, these individuals will have access to supervisors who are themselves specialists in supporting young people, and who can help to connect mentors and the young women they supervise to additional support as needed.

Young women in particular are experiencing increasing rates of mental health problems, self-harm and suicidal ideation. Usual care, as noted, is not standardised, and can be inaccessible, inappropriate, or subpar with respect to effectiveness for NEET young women specifically. We believe, and it is the opinion of the local authorities involved in this project, that this trial programme should lessen the adverse consequences these young women experience in association with being NEET. Trial involvement will likely increase the contacts this population of young women would typically have with professionals who can signpost them to sources of support as needed. Increased hope is robustly related to a plethora of positive outcomes. Yet irrespective of intervention allocation, it

is notable that youth populations very typically experience positive outcomes in randomised controlled trials, even if they do not receive any intervention. There are many reasons for this, including that there appear to be benefits of research participation such as a feeling of altruism, and that the experience of research assistant seems to be positive if not therapeutic in nature. Nonetheless, we accept that all research and especially that trialling new packages of interventions confers risks. We identify the following risks as "expected" in the sense that they are common to the population of young women, i.e., they are not "unexpected" in the target population. These risks are increased distress, self-harm, suicidal ideation, drug and alcohol use. In addition, although we believe it unlikely, we note that it is always possible that research and intervention procedures could result in distress.

11.2. Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical or psychological occurrence, unintended disease or injury, or untoward clinical signs in a participant taking part in the trial, whether or not they are related to the intervention or trial procedures.
Adverse Reaction (AR)	An adverse event that is judged by either the reporting investigator or the sponsor as having a reasonable possibility of a causal relationship (e.g. definitely, probably, or possibly related) to the any aspect of the study procedure (e.g. research assessments) or the HOPEFUL intervention (delivered at any duration). The degree of certainty on the relatedness of the study procedure or intervention and an adverse event will be classified as either "not related", "unlikely", "possible", "probably" or "definitely". AEs classified as possible, probable, and definitely related are considered an Adverse Reaction. • Not related: No evidence of any causal relationship. • Unlikely: There is little evidence to suggest there is a causal relationship (e.g., the event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g., the patient's clinical condition, other concomitant treatment). • Possible: There is some evidence to suggest a causal relationship. However, the influence of other factors may have contributed to the event (e.g., the patient's clinical condition, other concomitant treatments). Cases where relatedness cannot be assessed, or no information has been obtained, should be classified as possible. • Probable: There is evidence to suggest a causal relationship and the influence of other factors is unlikely. • Definitely: There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out beyond reasonable doubt.
Serious Adverse Event (SAE)	A Serious Adverse Event is an Adverse Event that is categorised as serious based on one (or more) of the following criteria: ● results in death ● is life-threatening ● requires inpatient hospitalisation or prolongation of existing hospitalisation ● results in persistent or significant disability/incapacity ● leads to foetal distress, foetal death, or consists of a congenital anomaly or birth defect

Term	Definition
	• necessitates medical or surgical intervention to prevent any of the above • is otherwise deemed medically significant by the investigator. Within TLFP, the following events will also be considered SAEs: • suicide attempts, defined as any act of deliberate self-harm/injury where the participant had intent to end their life; suicide attempts are considered SAEs regardless of whether the resultant harm was life-threatening or required hospitalisation • risk behaviours that require police involvement and/or arrest. • crisis care involving the ambulance service and/or presentation to an accident and emergency (A&E) unit. Notes: • The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. • Planned hospitalisations for a pre-existing condition, without a serious deterioration in health, would not be considered an AE or SAE.
Serious Adverse Reaction (SAR)	An Adverse Reaction (as defined above) that has resulted in any of the consequences characteristic of a Serious Adverse Rvent (as defined above).
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A Serious Adverse Reaction, the nature and severity of which is not consistent with the information known about the TLFP intervention or study procedures in the view of the investigator.

11.3. Recording and reporting of Adverse Events

There are two methods for detecting potential adverse events. First, an adverse event may be reported through a structured research assessment using the Adverse Event Checklist (both trial arms) or EDAPTS (HOPEFUL Together arm only). Second, a spontaneous disclosure by a research participant may suggest an adverse event. This may occur during verbal interactions involving a participant and a researcher, or during interactions involving a mentor and mentor supervisor.

When a member of the research team becomes aware of a possible AE (via any method), they will attempt to collect the necessary additional details to enable an accurate record and classification of the severity, relatedness, expectedness, and seriousness of the event. This might involve making further contact with the young women and/or mentor, the mentor supervisor, and any other relevant parties. Where possible, participants will be informed about the need to seek further information from other relevant parties (e.g., from a key worker). If the incident is currently occurring, the team member will prioritise dealing with any immediate safety issues in line with relevant safety protocols or urgent actions concerning the clinical care of participants. Risk of harm will be managed using the trial safeguarding procedures (see below). The researcher will, as soon as possible, record (and as required report) the potential Adverse Event.

All Adverse Events will be reported using the trial Adverse Event Reporting Form, which includes no personal data and will identify the participant only by their study ID. This will initially be completed by whomever identified the event, and then passed to the Chief Investigator (or delegate) as soon as possible for review and initial classifications of seriousness, relatedness, and expectedness . For non-serious adverse events, only Part 1 of the Adverse Event Reporting Form will be completed. If the event meets the threshold (or this is suspected) for a Serious Adverse Event, Part 2 of the Form will be completed. The Chief Investigator (or delegate) may send anonymised details of a suspected SAE to the DMEC Chair for an independent second opinion to reach consensus

of an SAE classification if required. If there is disagreement with any of the classifications, both should be recorded and the worst-case assessment should be used for reporting purposes.

An SAE will be reported to the Sponsor by the next working day after the CI/delegate becomes aware of the event. SUSARs will be reported to NHS REC within 15 days of the CI becoming aware of the event.

All AEs, SAEs, ARs, SARs and SUSARs will be pooled and reported to the DMEC at each meeting. This recording will include the number and nature of the events overall and split by trial arm. The TM will prepare this report with support from the project co-leads. It is the DMEC's responsibility on behalf of the Funder to monitor the number and the nature of these events and to ascertain whether there is any indication that the trial intervention is causing negative unintended consequences or harm.

11.4. Trial safeguarding policy

Lone working

Research staff may engage in lone working and/or visiting research participants in their own homes or community locations. At the point of referral, the research team will gather information from the referrer as to any risk/safety/safeguarding issues relevant to the referred participant and any issues related to potentially visiting this prospective participant in lone appointments or at home. Any information provided will be reviewed by a clinically trained member of the research team, who will assess and provide instructions to local research staff regarding how appointments with this young woman should be conducted. Assuming no information is provided by a referrer that contraindicates doing so, lone community visits may be conducted when the premises is staffed, e.g., staffed clinical/community support service or staffed residence. Home visits could be done by a single worker if a) the young woman was referred by an organisation that was able to confirm that there were no risk/safety/safeguarding or other issues precluding this, and b) the lone worker is not themselves vulnerable. Young women who self-refer, or for whom a referring organisation have provided information about potential risk or safety issues, will be visited in a pair and in a staffed clinical/community location. If this is not possible or appropriate, meetings will be held online or by telephone. The decision as to what meetings to offer for any potential participants for whom referrers indicate possible risk or safety issues will be made in consultation with clinically trained members of the research team. We will be able to draw on support from Clinical Research Network Research Delivery Teams, and this could include support to hold in-person assessment meetings. Any trial staff who were considered vulnerable, for example if pregnant, would not engage in lone community or home visits.

Research staff will additionally follow the lone/community working policies of their employing institutions (or this policy if the employing organisation does not have one that is suitable and up to date). These typically involve a buddying system, such that the manager (e.g., the TM for the Sussex Research Assistant (RA)), RCP, or the regional site lead (Berry, Forbes, Wilson), or another individual if the policy of the employing organisation, is notified of lone and/or home visits. A shared calendar would be used for this purpose. The visiting staff member would ensure that the calendar is populated with the participant's name, their address or the address of the meeting (e.g., if in a library or community centre), the start time and the end time, the RA's mode of travel (with details of registration if a car or other vehicle), and the onward location. There would be a call in/out policy and the nominated individual would take the steps as detailed in the employer's policy. These typically involve re-contacting the staff member at timely intervals (e.g., every 15 minutes) if they do not "call in" following the planned end time. After the amount of time indicated in the policy (e.g., one hour), the individual would call the participant, and if receiving no answer, would contact emergency services. Research staff will be informed of this policy, such that it should not be the case that the participant and/or emergency services are contacted unnecessarily.

Participant safeguarding

Adverse events will be recorded as described above. Researchers will take care to fully understand any adverse events reported to them. In addition to completing the paperwork and reporting these onward as indicated by the trial, they will also take care as to establishing the participant's safety and support. They will discuss with the participant as to services or other supports that have been engaged in relation to any adverse events. If no support has been engaged and the participant describes an ongoing or significant health or support need, the researcher

will discuss available and appropriate places that support could be sought. The researcher will establish whether the participant needs help to try and access these services. If so, the researcher will support the young person to engage this help, for example, encouraging the participant to discuss with a parent or carer. The researcher could, if this was requested by the young person, inform any service that the young person is currently engaged with about a new health need. For example, the researcher could contact the lead practitioner or duty worker if the participant is under the care of a youth service. The researcher will provide the participant with the debrief sheet which contains potential support organisations. The researcher will also discuss with the young person about informing their GP of the ongoing/significant health need and will offer the participant a copy of this letter.

In the event that a member of trial staff believes that a participant is at potential immediate and serious risk (i.e., risk to their own safety or posing a risk to someone else's safety), the participant would contact emergency services. The researcher would inform the participant about this and why they were contacting emergency services, i.e., explaining why they were concerned about the participant. If visiting the participant in person, the researcher would stay with the participant until emergency services arrived, or they would escort the participant into the care of a responsible individual who could wait with them. This could include a parent or carer or a youth or health service worker. If interacting with the participant on the telephone or via videocall, the researcher would use the same process and would ask to speak with the responsible individual to whom they were passing care or speak with emergency services before ending the contact. Researchers will also ask participants where they are physically at the beginning of any telephone or videocall in order to be able to provide this information to emergency services if it were needed.

Trial staff will be provided with risk and safety training by the TM, who themselves will receive training from the co-lead investigators. This training will teach them about the safeguarding policy and will help them to practice role-playing enacting this safeguarding policy.

12 STATISTICS AND DATA ANALYSIS

12.1. Statistical analysis plan

The statistical analysis plan for the definitive RCT analysis will be completed and signed-off, with review by the independent statistician on the TSC, before final database lock.

12.2. Summary of baseline data and flow of patients

In the feasibility Stage, participant flow will be reported using the Consolidated Standards of Reporting Trials (CONSORT) 2010 extension for pilot and feasibility trials[76].

For the definitive RCT Stage, participant flow will be presented using the CONSORT Statement 2010[77]. Descriptive statistics will be presented for sample characteristics and outcomes at baseline, by arm. We will descriptively analyse CSRI[57] data, characterising what constitutes usual support and how this may vary by area or arm.

12.3. Feasibility Stage Analysis

Progression to the definitive RCT will be decided using the above progression criteria (Section 3.1). Quantitative data will be evaluated with descriptive statistics (count, %, mean, median, SD, interquartile range) as appropriate. The amount of missing data will be reported. We will descriptively analyse CSRI data, characterising what constitutes usual support and how this may vary by area or arm.

12.4. Primary outcome analysis

The primary outcome, measured at 16 weeks, will be analysed using ANCOVA adjusting for baseline hope and other covariates considered *a priori* prognostic of outcome, with fixed effects for area, age (continuous), and arm. Analyses will follow intention-to-treat (ITT) principles. Additionally, multiple imputation will be applied to assess

sensitivity of results to missing data assumptions. We will conduct a complier average causal effect analysis for the primary outcome (using dose as defined in the Theory of Change). We will first summarise the extent of contamination descriptively and then, if contamination is identified, conduct a contamination-adjusted intention to treat analysis using an instrumental variables approach[78]. There will be separate analyses for the primary and secondary endpoints.

12.5. Secondary outcome analysis

Secondary outcomes will be analysed similarly to the primary outcome. We will present the estimated treatment effect, 95% confidence intervals, and p-values per outcome. There will be separate analyses for the primary and secondary endpoints. We will additionally compute relative risk and recovery rates (with associated 95% confidence intervals) for participants within each trial arm pertaining to participants moving from sub-threshold to over clinical threshold (incidence) and vice versa (recovery) for mental health symptom scores (PHQ-9[47], GAD-7[48], SIAS-6/SPS-6[49]).

12.6 Subgroup analyses

A subgroup analysis will be conducted with respect to age (comparing 18 years and under *versus* 19 plus, due to the transition from mandatory education and potential differences in usual support provision) and, as an exploratory analysis, baseline hope (comparing whether outcomes differ for young women who began more or less hopeful, considering specific differences according to self-agency and pathway components).

12.7 Mediation analysis

Mediation analysis will comprise testing the size and significance (using bias-corrected 95% bootstrapped confidence intervals) of indirect effects (final goal attainment (GBOT[58]), mentor relationship (WAI-SR[59]), and post-intervention hope (THS[23])) on 12-month outcomes, using path analysis with robust estimation.

12.8 Economic evaluation

The cost of HOPEFUL will be calculated based on youth-initiated mentor training and supervision. Health and social care support will be combined with appropriate unit costs and costs compared between arms. A societal perspective will also be used with time lost from employment valued using average wages and time lost from education included. With no established values on lost education, we will use a range of proportions of average wage rates to reflect impact on future returns. Follow-up cost comparisons will adjust for baseline using bootstrapped regressions. We will use the SWEMWBS well-being measure, for which a value set is available. Demographic and health predictors of short-term cost-effectiveness will be tested using net benefit regression to address equity issues. In addition to a cost-effectiveness analysis, we will conduct a cost-benefit analysis by comparing costs of the intervention and other support to the costs of lost work and education. While analysis. will focus on the trial period, we will also extrapolate costs and effects by assuming different scenarios based on employment/education outcomes at trial end. In our analyses, we will calculate care and support costs and treat these separately from the value of employment/education/training gains so as to avoid double counting. Similarly, when combining costs with well-being, we will focus on care and support costs. We do not propose to conduct a formal Distribution Cost-Effectiveness Analysis (DCEA) because this has so far been developed in a healthcare context and is particularly linked to models rather than trials as here. However, we will explore the cost-effectiveness of the intervention for different subgroups (e.g., defined by age) in order to gain insight into distributional issues.

12.9 Qualitative evaluation

Feasibility Stage:

Qualitative data will be analysed using a hybrid deductive-inductive-multi-perspective Thematic Analysis[79] approach. Deductive analysis will be used to identify markers of intervention acceptability[73]. Inductive analysis will be used to identify additional experiences pertaining to accessibility and feasibility, and other research and intervention experiences relevant to research questions, e.g., suggested changes to research protocols. The multi-perspective design[80] provides a structure for exploring individuals' experiences whilst considering subgroups

within the sample. We will use this approach to purposively sample participants with differing patterns of trial and intervention engagement and to compare their experiences within the presentation of results. The analysis will involve peer and non-peer researchers to help ensure that results themselves also form a multi-perspective understanding, facilitating greater depth of engagement and nuance in analysis and reporting whilst foregrounding the voices of NEET young women.

Definitive RCT Stage:

The qualitative process evaluation will use a multi-method multi-perspective approach. Qualitative analysis will involve a deductive-inductive-multi-perspective[80] Thematic Analysis[79]. The deductive analysis will be used to map experiences of the intervention and its outcomes to the Theory of Change model, and to identify experiences of the hypothesised mediators. Inductive analysis will be used identify broader experiences of the intervention, unintended outcomes, additional mechanisms of effects (and explanatory accounts of lack of effects if relevant), putative contextual moderators of implementation and outcome, and putative effects on usual service provision and other cost-related outcomes.

Feasibility and definitive RCT qualitative data will be sought on challenges of engaging with HOPEFUL and any dissatisfactions. Qualitative interview guides use Critical Incident Technique (CIT)[81] prompts to elicit information regarding unanticipated and dissatisfactory outcomes and how these arose, including precipitators, events, who was involved and how.

12.10 Data and Analytic Integration

We will integrate multiple data sources, methods, and analyses to answer our research questions (RQ).

Feasibility Stage:

We will establish the feasibility of doing an RCT of HOPEFUL plus usual support *versus* usual support alone (RQ1.1) and of using the youth-initiated mentor model (RQ1.2) by collecting data pertaining to pre-specified progression criteria. We will assess the quality of mentoring relationships (RQ1.2) using working alliance data. We will collect data on the primary outcome (hope assessed with the THS) to estimate the SD in NEET young women (RQ2.1). A mixed methods matrixing approach[82] will be used to chart convergence and divergence between quantitative and qualitative data pertaining to each research question, and to evidence relating to each individual progression criterion to ensure transparency of their satisfaction. It will also be used to identify if changes are needed to increase research and/or intervention acceptability and feasibility (RQ1.3 and 2.3). We will use qualitative data, analysed within a framework of acceptability, to identify explanatory accounts for areas needing development (e.g., green progression criteria that were not satisfied) and identify specific suggestions for improvements (RQ2.3). We will work with our oversight groups to confirm necessity and sufficiency of suggested changes to research and intervention protocols. Intervention amendments, if made, will be reflected in a refined Theory of Change.

RCT Stage:

We will test if HOPEFUL improves the outcomes of NEET young women compared to usual support (RQ3.1) by tabulating results from statistical analyses of the primary outcome (hope; THS) and secondary outcomes (SWEMWBS, PHQ-9, GAD-7, TUS, GHSQ) at primary (16-weeks) and secondary (12-month) endpoints and the cost-effectiveness analysis using CSRI data. We will produce descriptive data on adverse events and integrate these data with qualitative accounts of unintended consequences and we will integrate quantitative and qualitative data to identify how NEET young women and mentors experience HOPEFUL and its effects, safety, and acceptability (RQ3.2). We will integrate statistical outcome findings alongside qualitative process evaluation data in a mixed-methods matrix to map the effects of intervention and identify convergences and divergences, including between the measured outcome effects and NEET young women and mentors' first-hand narrative accounts. We will tabulate the results of statistical mediation analysis (GBOT, WAI-SR, THS) (RQ4.1). We will present a summary of these results alongside the qualitative analysis of mechanisms and putative moderators (RQ4.2), identifying convergent and divergent evidence, in a mixed-methods matrix of mechanisms and contextual moderators of intervention effects.

13 DATA MANAGEMENT

13.1. Data collection tools

We will collect all directly from the participants using the enclosed data collection tools. We will not use medical notes or other informant sources. Assessments may be completed in person, via telephone or videocall, or via online self-report. Paper-based versions of the assessments will exist for flexibility of data collection, but data will be entered directly into REDCap wherever possible. Data that are collected on paper will be transferred into REDCap as soon as is possible. The young woman's record on REDCap therefore functions as the Case Report Form.

13.2. Data handling, data protection and patient confidentiality

The trial will be compliant with UK Data Protection Legislation through collecting only the minimal personal data needed for the trial to effectively run, by being transparent about the collection, storage, and use of all data that are collected, and by ensuring that all data storage and transfer are done securely. All investigators and trial site staff will comply with the requirements of UK Data Protection Legislation with regards to the collection, storage, processing and disclosure of personal information. The data custodian will be Dr Clio Berry, Brighton and Sussex Medical School. The sponsor requires that data are stored for a minimum of five years after publication. The funder strongly supports the public sharing of full research data sets, see below for details.

The Brighton and Sussex Clinical Trials Unit (CTU) uses the REDCap system for data collection and storage. Trial staff will have an individual password-protected account that is tailored to their role on the trial. Using this system, the CTU will maintain an audit trail of data changes ensuring that there is no deletion of entered data, maintain a security system to protect against unauthorised access, maintain a list of the individuals authorised to make data changes, maintain adequate backup of the data, safeguard the blinding of the trial and archiving of source data. If data are transformed during processing, it will be possible to compare the original data and observations with the processed data. We will use an unambiguous participant identification code that allows identification of all the data reported for each participant. Data will be managed by the CTU according to their standard operating procedures. Data will be reviewed and cleaned regularly by a member of the data management team.

Local trial staff (i.e., RAs) will enter data into REDCap. They will be trained and supervised in doing so by the TM. Local trial staff will additionally record local data that will not be entered into REDCap. Local data will include personal data about research participants. These data will be stored using an electronic system called Box to which the sponsoring organisation has an institutional licence. Box is compliant with UK Data Protection Legislation and allows for version control and secure collaboration within and external to the sponsoring organisation. These data will be stored in a Trial Master File that is organised and maintained by the TM. Trial staff will have an individual password-protected account that will be linked to their institutional email address. Trial staff will be trained and supervised in using Box by the TM. The TM will additionally maintain a Trial Management File, to which no blinded research staff have access. This file will contain data and documents that pertain to the unblind aspects of the trial, including mentor participant personal data. Access to sub-folders of the file will be given to relevant staff (including peer researchers conducting qualitative interviews).

Any paper copies of trial paperwork, such as consent forms or assessment booklets, will be stored securely at the local site; university or NHS premises. These documents will be stored in locked filing cabinets in controlled rooms, i.e., behind an access card or pin system to which only individuals in the employing department have access. Any personal data will be stored independently of any research data. We will use a professional transcription service (an approved supplier of the sponsor for this purpose) to transcribe qualitative interviews. Once transcribed, we will anonymise the transcripts and securely delete the audio files. All research data will be archived and then destroyed after 10 years after publication, with an anonymised derived version of the final data available on a public data sharing site as per the funder's request. All personal information will be destroyed within two years of the study end date.

13.3. Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits, and inspections- in line with participant consent. An anonymised derived version of the final data will be made available on a public data sharing site as per the funder's request.

13.4. Archiving

Archiving will be authorised by the Sponsor following submission of the end of trial report. All essential documents will be archived after 10 years following the completion of trial and publication of the final report. Destruction of essential documents will require authorisation from the Sponsor.

14 MONITORING, AUDIT & INSPECTION

The sponsor monitors the conduct of research that it sponsors. The trial programme is eligible for NIHR portfolio eligibility. Therefore, recruitment activity will be audited as per standard protocol for all NIHR portfolio activity in England. This auditing is usually completed by the Local Clinical Research Network (LCRN) appropriate to the region in which the research activity takes place, i.e., Kent, Surrey, and Sussex and/or East of England in the present case. This auditing would only involve recruitment numbers and dates recruited, it would not involve any research or personal data sharing or access of any kind. In addition, it may be that external organisations involved in the trial want to use their own monitoring processes. For example, the local authorities and/or charities may hold individual records of research activity within their catchment areas. Such monitoring activity is the responsibility of these external organisations and will not interfere with the trial activity.

15 ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Authorisations and permissions

Clinical Trial Authorisation (CTA) is not required. Typically, local authorities and charities do not have their own internal or formalised processes for providing research governance and will support projects that have university approvals in place. Should we add any additional organisation as a referring/mentor supervising partner, we will ensure that we establish if they do have any internal research governance approvals processes and that we complete these before any research activities occur in these organisations. Following approval from the Health Research Authority and NHS Research Ethics Committee, confirmation of capacity and capability will be sought from Norfolk and Suffolk NHS Foundation Trust before giving the trial the greenlight to open in this locality. Any GP PICs will provide their own permissions for becoming involved in the trial and can receive assistance in this matter from the Local Clinical Research Network.

15.2. Amendments

Amendments will be notified to the sponsor and then, upon receipt of a signed amendment form, will be submitted to HRA via the amendment system. Any research team or oversight committee member may raise a query regarding a potential need for amendment. The decision to enact amendments resides with the co-project leads. The co-project will aim to discuss potential amendments with other parties as relevant due to their nature. For example, the co-project leads would aim to discuss any suggested amendment that altered the research procedures experienced by NEET young women with the PIP. Amendments will not be instituted until they are approved. Once approved, amendment documentation will be circulated to trial staff and any necessary training will be arranged. Trial staff will then implement the amendment in practice. Amendment documentation will be saved in the site file and amendments will be summarised in writing within this study protocol. Amendments will be identified, as part of regular meetings/reporting procedures, to the DMEC and TSC oversight committees and

to the funder. More substantive amendments, as relevant, would be communicated to any other parties if necessary. For example, in the very unlikely event this was to occur, changes to trial eligibility criteria would need to be communicated with referring organisations.

15.3. Peer review

The output from the ADA development award, including the intervention blueprint and Theory of Change model have been independently peer-reviewed as part of the submission to the PLOS One journal[32]. Subsequently, the trial protocol has already been subject to high-quality peer review, including expert and independent peer review. Three independent reviewers from the PHRADA panel peer-reviewed a truncated version of the trial protocol at the first stage of applying for funding. This included expert researchers and health economists. The full trial protocol was then reviewed by the stage one and then the stage two NIHR PHR funding panel. Moreover, we additionally received five pre-stage two panel reviews from independent experts who were not part of the stage two panel. Subsequent to the stage two panel recommendation to fund, we received a further post-panel independent review from an unidentified number of independent reviewers. In addition, this protocol and the accompanying documents were reviewed by the sponsor. This included a Pre-Sponsorship Review Panel comprising academic and clinical researchers, governance and public members, and a sub-committee of the Sponsor.

15.4. Public and Patient Involvement

This proposal reflects the next stage following our NIHR PHR funded Application Development Award (ADA[32]). The ADA was designed with co-applicant Fountain, who is a lived experience expert in parenting a NEET young woman and in patient and public involvement practice. In the ADA, Fountain was involved in research team meetings and project decision-making, attended Study Steering Committee meetings, co-presented to youth involvement panel meetings, and contributed to ADA outputs including the written report[32]. The ADA used a participatory co-production approach. NEET young women, their relatives, and practitioners across a range of services, participated in formative research interviews to explore the needs of NEET young women and to reflect on the potential for a hope-focused intervention. Next, NEET young women took part in co-design sessions to develop the ideas from the interviews and from our previous review of hope-focused interventions in youth depression, itself collaboratively conducted with a youth lived experience panel. Practitioners then participated in a Theory of Change workshop in which they refined the intervention model and identified its short, medium, and long-term outcomes. Two peer researchers, young women with experience of social and occupational withdrawal and mental health problems, supported the data collection for the formative interviews and independently ran all the co-design sessions with NEET young women. The peer researchers contributed to the analysis of stage 1 interviews and preparation of the materials for the co-design sessions, led the co-design analysis of the co-design sessions, and contributed to creating the ADA outputs. We also engaged the "Youth Cafe"[83] lived experience research consultation panel hosted by a Sussex Partnership NHS Foundation Trust. Berry and Fountain presented to this panel twice; once to consult on the production of materials designed to promote the study and to refine the recruitment and data collection procedures, and again at the end of the project to consult on a draft of the intervention blueprint. Finally, we engaged a parent of a NEET young woman as a consultant, with Fountain supporting them to review the intervention blueprint.

Resultant changes arising from our public involvement work are reflected in this proposal. These are: targeting hope as the primary outcome and not centring the intervention on mental health symptoms or on education, employment, and training; first focusing on enhancing positive sense of self and meaningful activity (intervention Module 1) before moving to an explicit focus on hope (Modules 2-6); offering the intervention materials to control arm participants. Fountain has been involved in all stages of developing the current proposal, including design decision-making, formulating the public involvement plan, writing, and editing this application and the attached detailed research plan.

In this project, public involvement will be integrated in multiple ways. Co-applicant Fountain co-developed the current proposal and public involvement plan, having led public involvement in the ADA in which the HOPEFUL intervention was developed. We aim to foreground the voices especially of NEET young women, but also those who support them, in multiple roles to ensure that public involvement imbues design, delivery, data collection and analysis, oversight, and dissemination. The Public Involvement Panel (PIP) will be hosted within Sussex Partnership NHS Foundation Trust (SPFT), where Fountain is employed. This is appropriate because it provides the PIP with a sense of separation and independence from Fountain and the research team. Moreover, the Trust

has mechanisms to appropriately employ, pay, and support public members using expertise developed over many years involving lived experience experts in various complex research projects. All public advisors will be paid for their time and necessary travel and other expenses. The rate of payment is £25 per hour as this is standard for public involvement activities in NIHR-funded projects. Public involvement will be embedded in this study in the following ways:

- RESEARCH MANAGEMENT: Fountain has lived experience of parenting a NEET young woman and was centrally involved in the design of the ADA as a co-applicant/co-investigator. Building on this prior role, Fountain will support to the public members of the Study Steering Committee and supervise the PIP co-ordinator. Fountain will contribute to regular research team meetings and participate in all project decision-making.
- PUBLIC INVOLVEMENT PANEL (PIP): A PIP specific to this project will be created that will comprise approximately 8 young women with recent experience of being NEET (e.g., within c. last 5 years), aiming to represent the geographical areas involved in the project. The PIP will be co-ordinated via Sussex Partnership NHS Foundation Trust (SPFT) by a facilitator who is herself a young woman with relevant experience e.g., social and/or mental health problems. Thus, the PIP will maintain some independence from Fountain and other research team members. We convened the panel before in the pre-funding period to authentically involve the PIP in preparing draft materials prior to submission for ethical review, including co-developing qualitative interview guides, adapting the adverse events scale, and informing website development. The PIP will then meet c. two weeks before the other oversight groups, with PIP meeting minutes shared with these committees before their respective meetings. Meeting 2 will provide a detailed introduction to the project timetable and ongoing role of the PIP. Meeting 3 will review necessary protocol changes prior to definitive RCT commencement. Meetings 4-9 will involve document and progress review, co-developing RCT qualitative interview guides, consultation on necessary amendments following the feasibility trial, and informing recruitment, retention, and dissemination strategies. Training will be provided during a role induction meeting by the PIP co-ordinator, and additional training (e.g., research methods) on a bespoke basis as per individual need.
- STUDY STEERING COMMITTEE (SSC): Approximately two of the SSC will be public members. These roles will be taken by individuals with recent experience of being a NEET young woman and/or supporting NEET young women. Fountain will provide a role induction meeting and offer pre- and post-meeting support. Additional training (e.g., in research methods) will be provided by the research team according to individual needs analysis.
- EVALUATION: We will capture and evaluate involvement activities and outcomes using a log, maintained by Fountain and the PIP co-ordinator in discussion with PIP, SSC public members, and peer researchers.
- DISSEMINATION: We will use the GRIPP-2 framework[76] to comprehensively report involvement activities and outcomes, contributing to the creation of transparent and high-quality public involvement evidence, in our scientific outputs. Fountain will co-author these outputs. We will report on involvement in non-academic outputs in addition. As well as review at regular PIP meetings, costs are included for PIP members (at preference) to have a more substantial role in co-producing dissemination outputs (e.g., animated videos) and to create a video and presentation specifically about the role, experiences, and impacts of the PIP itself. These outputs will be made available through our public website and promoted widely. Costs are sought to enable two public members to present, with support, at an inter/national conference.

In addition to the public involvement activities described above, we will amplify the voice of NEET young women in data collection and analysis. We will employ three peer researchers who are young women with recent experience of being NEET to collect qualitative interview data from NEET young women and be involved in qualitative data analysis.

15.5. Protocol compliance

Compliance will be assured using the following approaches. First, we will employ a fulltime Trial Manager (TM) who will (under support and guidance from the project lead) monitor and ensure protocol compliance. Second, we will provide comprehensive training and supervision to trial staff, with a focus on protocol compliance and data security. All trial staff will receive regular individual supervision. The TM will additionally hold a c. weekly meeting in which Research Assistants (RAs) will discuss their recruitment, retention, and assessment practice. These meetings will have the dual purpose of providing support to trial staff and ensuring ongoing protocol compliance. Third, although we will provide flexible means of participation (e.g., in-person versus telephone versus videoconference versus self-completion of trial assessments), we will use carefully curated systems to collect and

record data. We use standardised assessments to collect trial outcome and quantitative process evaluation data. We will administer these assessments using REDCap software. This software will minimise errors in data collection (such as impermissible values) and maximise response accuracy. Fourth, an eligibility check will be performed before each participant (NEET young woman) is deemed eligible.

All trial staff and other research team members will be instructed to report any suspected/actual protocol deviations to the TM, regional lead (who will report onward to the co-project leads immediately) and co-project leads. Once assessed by the co-leads and TM and confirmed as protocol deviations, these events would be reported onward. All significant protocol deviations will be reported to the sponsor the next available opportunity to the TSC and DMEC.

15.6. Financial and other competing interests

No disclosures.

15.7. Indemnity

The University of Sussex has cover in place to meet the potential legal liability for harm to participants arising from the design, management, and conduct of the research. The certificate is available here: https://www.sussex.ac.uk/webteam/gateway/file.php?name=sussex-professional-negligence-(research-teaching-and-consultancy)-certificate.pdf&site=262

15.8. Access to the final trial dataset

Access to the full trial data during the trial will be controlled by Brighton and Sussex CTU. A copy of the full dataset will be provided to the trial statistician for the purposes of feasibility analysis and later for the purpose of outcome analysis. Access to the full dataset will additionally be provided to the economist for the purposes of feasibility and outcome analysis. The co-lead investigators and the TM will be provided access to the full dataset as needed to help clean data or answer data queries during analysis. Following outcome analysis, an anonymised derived version of the full trial dataset will be made available to the public in the sponsor's (or another if more suitable) repository. A data dictionary will be provided to aid in data use.

16 DISSEMINATION POLICY

The key outcomes of this trial programme are feasibility, effectiveness, and cost-effectiveness data on HOPEFUL. We will produce the following specific outputs:

1. Public website disseminating finalised paper and digital versions of (1) the HOPEFUL intervention young person workbook, (2) mentor intervention manual, (3) mentor training package, (4) mentor supervision guidance package, and (4) intervention theory of change with implementation toolkit,
2. Effectiveness data on HOPEFUL (RCT) in publicly accessible dataset,
3. Academic; FT protocol (1), outcome paper (2), RCT protocol (3), outcome (4), mechanisms paper (5),
4. Non-academic; One infographic presenting FT findings (1) and one for RCT (2), One animated video presenting FT findings (3) and one for RCT (4), One PIP video (5) and presentation slide deck (6).

We will create the above academic publications which, as is typical for our team, will be published in a timely fashion in high-quality, impactful publications. We will hold dissemination events for the FT and RCT. We will use these events to accelerate interest in joining a NEET young women Community of Interest (COI) that we will create and maintain. We will regularly engage electronically with the COI, advertising the project, providing news and updates, and promoting the finalised intervention package and implementation support materials (assuming intervention superiority or non-inferiority). West Sussex County Council, the Prince's Trust, YMCA Sussex Downslink, and The Girls Network national mentoring charity have already requested to join the COI. Alongside our outputs, we will create tailored policy briefings to help drive national interest. Using the research team's extensive networks and Impact Panel support, we will publicise our events, the COI, project outputs, and policy briefings widely. We will especially focus on stakeholders relevant to NEET policy and to provision at national,

regional, and local levels. These include commissioners, local authorities, the Local Government Association, the Office for Health Improvement and Disparities, voluntary and charity organisations, e.g., Young Minds, ICBs, ARCs, NHS England, the AHSN, and networks like the Surrey & Sussex Women's Health Research Network. To scaffold HOPEFUL implementation at the end of the RCT, we will hold workshops in the five local authority areas that participate in the project. In these workshops, local authorities, voluntary and charity organisations will work with the research team to identify and agree ongoing implementation actions and responsibilities. We will share workshop outcomes in the form of case studies, promoting them via our dissemination events, the COI, and to policymakers and commissioners to stimulate interest in wider national implementation of HOPEFUL. We will consult with our SSC and PIP on dissemination strategies to support creative approaches.

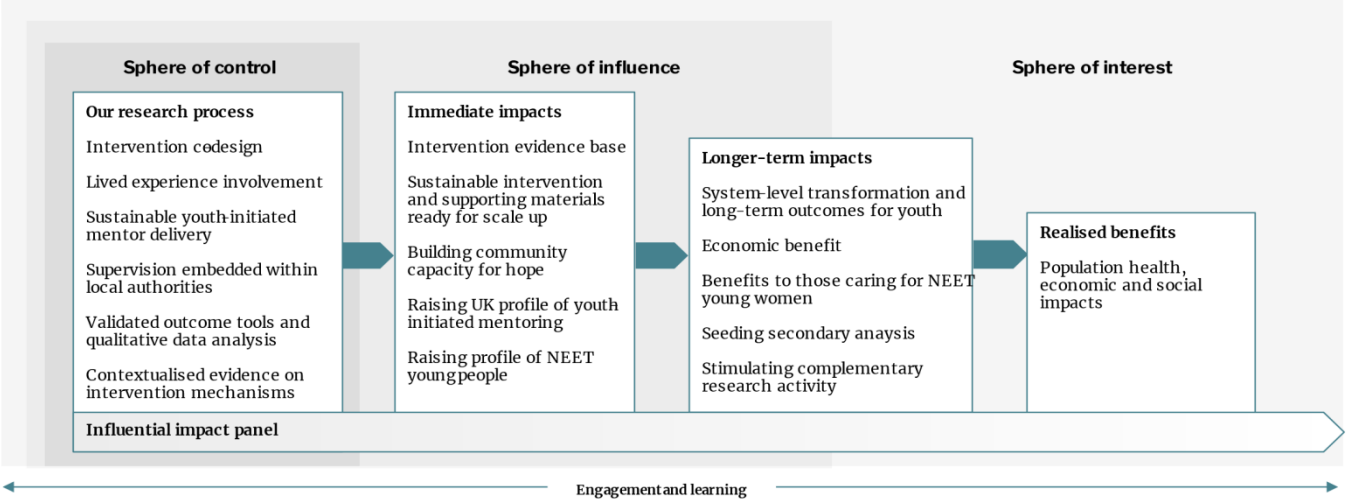
We will create a publicly accessible website that houses all project information relevant to prospective participants and as per public interest in the research. We will use this website and complementary social media accounts to share progress and findings in a timely and engaging fashion. We will create a digital strategy to engage with relevant youth-facing networks and drive public, including NEET young women's, interest and thus traffic to the public website. During the project, we will create a regular newsletter to inform research participants about study progress and will share this with them in their preferred form (paper/digital). We will create videos that showcase project findings at key points and share them with research participants and the public including NEET young women through the public website. We will review these strategies with the PIP and refine as needed to support creative and inclusive engagement with research participants.

17 IMPLEMENTATION AND IMPACT ORIENTED ACTIVITIES

HOPEFUL has been designed to be supported by a non-specialist in a structured mentoring role. The outputs of the current project include all supporting materials needed to implement and use HOPEFUL. We have worked with professional stakeholders in the ADA, and in the preparation of this proposal, and have confirmed that there would be minimal change required of user organisations for the scale up of this intervention. The professionals all reported a high level of interest in HOPEFUL being something they could offer as part of their usual provision. The youth-initiated mentor model means that minimal professional staff resource is required to offer HOPEFUL at scale. Local authorities, and voluntary and charity organisations, confirm that youth workers can feasibly supervise mentors alongside their usual practice within the proposed research and on an ongoing basis, should the intervention prove effective and cost-effective.

NEET young people and coastal deprivation are key current national and local priorities. HOPEFUL has been designed to focus on the pursuit of NEET young women's personally meaningful goals, which fits with the youth-centred ethos of high-quality youth support services[84]. HOPEFUL can be tailored to different sociocultural and institutional settings, as mentors are selected by NEET young women themselves, and the intervention is deliverable using selectable and adaptable tasks and activities over a flexible number of sessions. We have proposed to evaluate the model in five coastal areas that all have high numbers of NEET young people, but with varying health systems and population socio-demographics and reflecting different sociocultural and institutional settings within which HOPEFUL would then be scaled up. Issues related to potential moderators of intervention accessibility, implementation, and outcome will be explored in the proposed research. We will engage local authorities and relevant partners in a series of workshops to agree context-relevant responsibilities and actions for implementation. The low implementation cost would not commit any organisation to a large outlay before witnessing benefits in practice. Guidance for ongoing monitoring and evaluation will be provided as part of implementation supports available on the public website.

The potential for impact, summarised in the figure below, has been conceptualised using the refined method for theory-based evaluation of the societal impacts of research[85].



17.1. Immediate (within 12 months)

- INTERVENTION EVIDENCE BASE: Our research will increase understandings of support needed to raise the hope, reduce mental ill-health, and improve socio-occupational functioning of NEET young women. This evidence-base, with the support of the Impact Panel, will guide policy, commissioning, and practice decisions in local authorities nationally, facilitating more cost-effective decisions and better value for public money.
- SUSTAINABLE INTERVENTION AND SUPPORTING MATERIALS READY FOR SCALE UP: Our research will validate the intervention model, which was designed in consideration of scale-up potential, and enable the creation and dissemination of implementation support materials. Our research team includes specialists in UK (Wilson) and low- and middle-income countries (LMICs)-based (Michelson) youth mental health care, which present key additional contexts within which the intervention could be scaled up and implemented.
- BUILDING COMMUNITY CAPACITY FOR HOPE: Our research will galvanise expertise and support for hope enhancement within the local authorities and surrounding communities in which the project is conducted, as well as, through our dissemination strategies, create a national appetite for growing community hope.
- RAISING UK PROFILE OF YOUTH-INITIATED MENTORING: Task-sharing (in which non-specialists are deployed to undertake specific health service roles instead of relatively scarce and expensive professionals) is a common evidence-based strategy for mental health service delivery in LMICs. There has been less research involving such approaches in the UK. Within the ongoing lack of youth provision, and the rising prevalence of mental health problems and NEET status, such approaches could improve UK population health on a large scale. This project is the first known evaluation of youth-initiated mentoring as one such approach. Our dissemination strategies will stimulate interest in its scaled-up use.
- RAISING PROFILE OF NEET YOUNG WOMEN: Our ADA found that NEET young people are subject to negative views including about their agency, aptitude, and work ethic. The intervention to be evaluated is explicitly focused on hope, primarily defined in relation to hopeful self-agency, and was developed in a participatory co-design process with NEET young women. Successfully completing a trial involving NEET young women as research participants and lived experience experts will further challenge these prevailing attitudes. Instead, it will demonstrate NEET young women engaging in effortful activities aimed at improving their lives and those of other NEET young women in the future, and generating evidence about how such improvements can be achieved. Our research, including outputs, local authority workshops, dissemination events, and the COI, will raise the profile of NEET young women within the national youth, education, health, and social care sectors, and stimulate interest in this group and the refinement of provision to better enable them to thrive.

17.2. Longer-term (1 to 5 years)

- SYSTEM-LEVEL TRANSFORMATION AND LONG-TERM OUTCOMES FOR YOUTH: With the support of our impact panel and oversight groups, we will feed directly into the Mental Health Community Transformation Programme, 16-25 pathway transformation, and public health guidance. Assuming effectiveness and cost-effectiveness, the uptake and implementation of HOPEFUL will provide much needed access to sustainable context-sensitive intervention for NEET young women. In turn this will enhance hope, reduce, and prevent mental ill-health, and

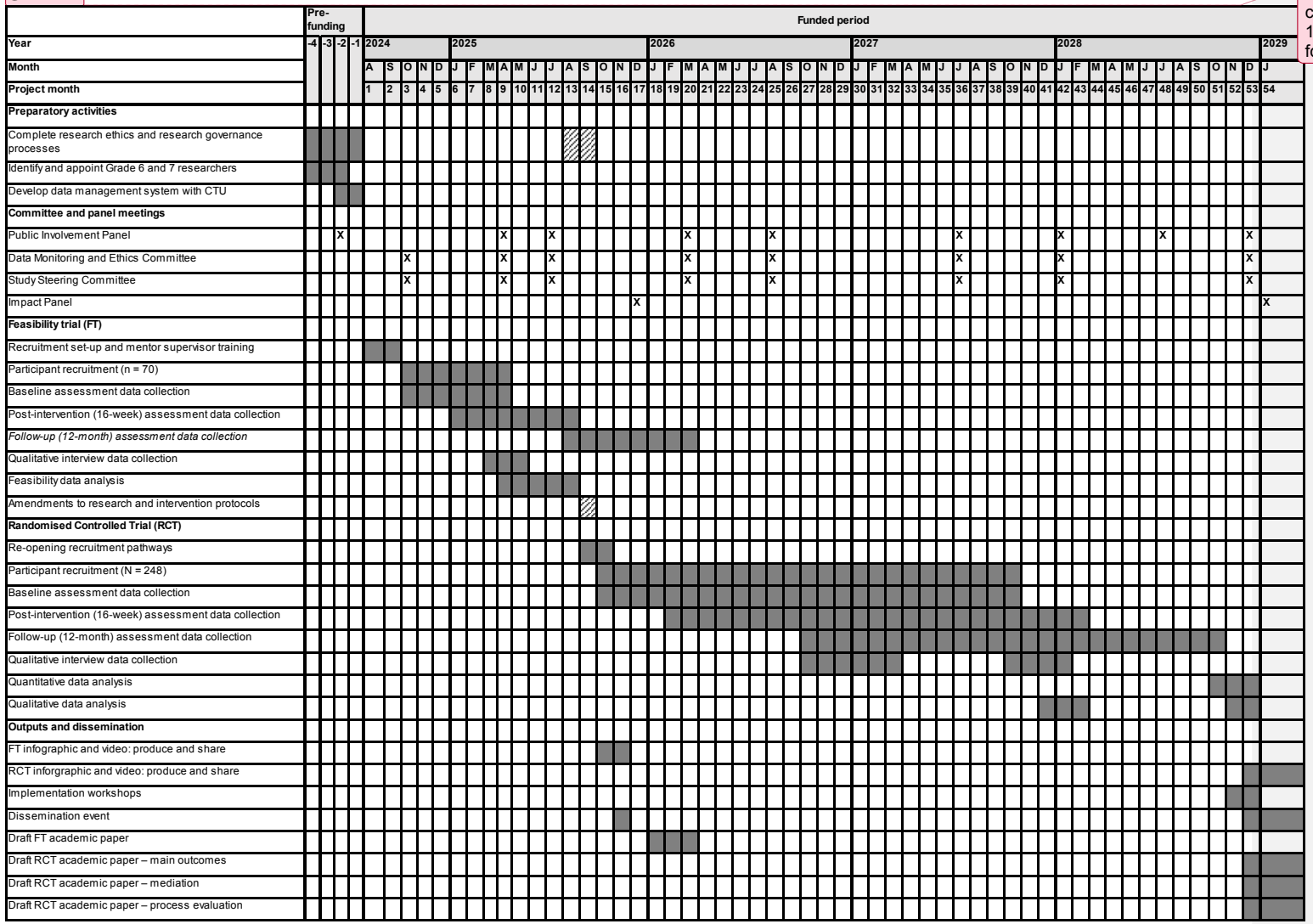
improve (re)engagement with education, employment, and training whilst also improving social connectedness of the sizeable and growing population of NEET young women.

- ECONOMIC BENEFIT: We expect our economic findings to inform changes (including influence on policy) that will increase rational decision-making and effective use of public money with respect to NEET-young women.
- BENEFITS TO THOSE CARING FOR NEET YOUNG WOMEN: Intervention outcomes will benefit supporters of NEET young women, through reduced hours spent in caring and accompaniment, and reduced need for financial help. Our data will provide indicators of the scope of such gains as extrapolated from the project sample.
- SEEDING SECONDARY ANALYSIS: The quantitative RCT dataset will be made available in a public repository for other researchers to use in secondary analysis. This will be a unique and valuable dataset considering the existence of only 15 known studies that offer gender/sex disaggregated data on English NEET young people and little additional data from other countries in addition.
- STIMULATING COMPLEMENTARY RESEARCH ACTIVITY: A successful trial with NEET young women will stimulate national and international appetites for research with this group and other marginalised and withdrawn youth; undermining the notion of such groups as “hard to reach” and emphasising that sensitive models and research protocols can make research accessible to underserved and neglected groups.

17.3. Impact Panel

We will convene a panel of influential individuals and organisation representatives with the expertise and networks to accelerate impact through influencing policy and commissioning on a national level. The Impact Panel will inform the dissemination strategy and promote project events, outputs, and the COI. The chair of this panel will be Politician Norman Lamb. Membership will comprise influential individuals such as coastal ARC implementation leads including Becca Randell, ARC Kent, Surrey & Sussex. The Impact Panel will meet twice in the project, with email support in between as needed. They will identify key actions for accelerating the possible impacts of our work and agree panel responsibilities and/or connect the research team to other relevant supporters.

18 GANTT



Commented [CR2]: GANTT version 4 inserted with changes reflecting: delayed recruitment start, feasibility 12 month follow up data collection, correction to error for end of RCT participant recruitment period.

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